

POINT OF CARE
TESTING

Roche *OMNI C*

Instructions for Use





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– Important information! – Always follow! –

These Instructions for Use contain vital warning and safety information.

This instrument is intended to be used only for the specialized purpose described in the instructions. The most important prerequisites for use, operation, and safety are explained to ensure smooth operation. No warranty or liability claims will be covered if the instrument is used in ways other than those described or if the necessary prerequisites and safety measures are not observed.

The instrument may be operated only by persons whose qualifications enable them to comply with the safety measures that are necessary during operation of the instrument.

Adjustments and maintenance performed with removed covers and connected power may be attempted only by a qualified technician who is aware of the associated dangers.

Instrument repairs are to be performed only by the manufacturer or qualified service personnel.

Only accessories and supplies either delivered by or approved by Roche are to be used with the instrument. These items are manufactured especially for use with this instrument and meet the highest quality requirements.

Operation of the instrument with solutions whose composition is not consistent with that of the original solutions can negatively affect, above all, the long-term measurement accuracy. Deviations in the composition of the solutions can also decrease the service life of the electrodes.

The quality control requirements must be completed at least once daily for safety reasons. Because accurate measurement results depend not only on the proper functioning of the instrument, but also on a number of other factors (such as preanalytics), the results produced by the instrument should be examined by a trained expert before subsequent decisions are reached that are based on the measurement values.

Explanation:



Meaning: "Caution, refer to accompanying documents".

– Important information! – Always follow! –

– Operating safety information –

- The instrument has been constructed and tested according to the protective measures stipulated by EN 61010-1: 1993 / IEC 1010-1 for electrical measurement, control, IVD, and laboratory instruments and was delivered from the factory in flawless condition with regards to safety features. In order to preserve this condition and ensure safe operation, the user must respect the notices and warnings that are contained in these Instructions for Use.
- This instrument is classified under the protection class I according to EN 61010-1 / IEC 1010-1.
- The instrument meets the conditions for overvoltage category II.
- The instrument meets the conditions for contamination level 2.
- Do not operate the instrument in an explosive environment or in the vicinity of explosive anesthetic mixtures containing oxygen or nitrous oxide.
- If an object or liquid enters the internal areas of the instrument, remove the instrument from its power supply and allow an expert to check it thoroughly before using it again.
- The instrument is suitable for long-term operation indoors.

CAUTION:

- The power cord may be plugged into a grounded socket only. When using an extension cord, make sure it is properly grounded.
- Any rupture of the ground lead inside or outside the instrument or a loose ground connection may result in hazardous operating conditions. Intentional disconnection of the grounding is not permitted.
- The instrument is not suitable for operation with a direct current power supply. Use only the original mains plug delivered with the Roche OMNI C.

– Operating safety information –

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1 Introduction



Fig. 1

The Roche OMNI C is a modular analyzer for measuring blood gases, electrolytes, total hemoglobin, oxygen saturation and hematocrit in whole blood, serum, plasma, acetate and bicarbonate containing dialysis solutions, and QC materials.

It is possible to complete database procedures or to make simultaneous adjustments during measurement or calibration.

The individual, mutually independent operating modes are defined as follows:

- a) Analyzer: measuring, QC, system, calibration, commonly used functions
- b) Database: data about patients, measurement, calibration, QC, and the instrument
- c) Setup: instrument settings
- d) Info: Roche info, version number, fill levels, help, sensor report

The Roche OMNI C is currently available in the following configuration:

- BG (pH, PO_2 , PCO_2) / ISE (Na^+ , K^+ , Cl^- , Ca^{2+}) and tHb/ SO_2

A new and patented fluid calibration system eliminates the need for expensive calibration gases. This change results in easier handling, a smaller footprint, and reduced costs.

An easily understood "Touch Screen" interface facilitates easy operation and saves costly and time-consuming user training.

The patented electrodes are completely maintenance-free, and only require a very small sample volume.

1.1 General notes

1.1.1 Application area

The instrument is designed to measure BG / ISE / tHb/SO₂ in whole blood. The accuracy of measurement values is checked accordingly.

In order to achieve accurate measurements of recommended aqueous control solutions (with regards to deviations from biological samples), choose the proper components and make the corresponding corrections in the QC measurement mode.

The accuracy of measurement values of undefined aqueous solutions cannot be guaranteed (e.g. due to the possibility of interfering components and/or missing or insufficient buffer systems, and/or differences in ionic strength and diffusion potential when compared to biological samples).

1.1.2 Operating instructions

The Roche OMNI C should be enabled at all times!

If the instrument will remain turned off for longer than 24 hours, it is necessary to carry out shutdown procedures (for more information, please see chapter 1.8, "**Installation**" and 1.9 "**Shutdown**").

Prevent fluids leaking inside the analyzer.

Complete at least one quality control test every day (please see chapter 5, "**Quality Control**", for more information) in order to quickly recognize error functions in the Roche OMNI C.

1.1.3 Symbols



This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices.



Lot number

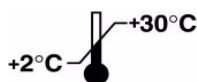


Expiry date

Electrodes: use by..
(The electrode must be inserted before the indicated date, but can remain in the instrument after the date)

Solutions: use by..
(The solution must be completely consumed by the indicated date)

If a day is not indicated, apply the last day of the respective month.



Storage note:

The conditions necessary to preserve the product's shelf life before opening.



For in vitro diagnostic use



Danger symbol: "Irritant" (on the label and packaging of the C3 solution)

Rating: Although not corrosive, momentary, longer-lasting, or repeated contact with skin or mucous membrane may result in inflammation. Danger of sensitization during contact with skin (when classified with R 43).

Caution: Avoid contact with eyes and skin, do not inhale vapours.



"GreenDot" (in Germany)



Manufacturer—according to IVD guidelines



Store upright



(according to the standards IEC 61010-2-101)—Risk of Infection!



Reference and/or catalogue number



CAUTION: refer to accompanying documentation!



Please read pack insert / instructions for use



Serial number (model plate)

Used in the Instructions for Use



All sections / passages that are marked with this symbol (refer to Instructions for Use) describe information to avoid possible potential for personal injury (for patients, user or third person).



Risk of infection!



All sections / passages that are marked with this symbol describe procedures and/or indicate conditions or dangers that could damage or lead to a malfunction in the Roche OMNI C, and which therefore should never be attempted.

TIP: *All sections / text locations marked with "TIP" describe safe procedures that are intended to provide the user with additional "Help."*

1.2 Measurement and calibration procedure

1.2.1 Measurement procedure

Use the following procedures to calculate the various measurement variables:

PO_2 : Use of the Clark measurement principle: measurement of current generated by the reduction of oxygen

PCO_2 : Use of the Severinghouse principle: potentiometric measurement of the pH change in the electrode caused by CO_2 .

pH-, Na^+ -, K^+ -, Ca^{2+} - and Cl^- are potentiometric electrodes. Special glasses are used as the sensitive element for pH and Na^+ . The potassium and calcium membranes contain special neutral carriers. A special ion exchanger is used for chloride membranes. Calculation of these variables also requires the use of a reference electrode—a permanently contacted chloride electrode in the Roche OMNI C.

tHb / SO_2 : Light absorption in whole blood is measured at four different wavelengths, whereby on one hand the sample is subjected to light radiation and on the other hand the dispersed light is also evaluated.

Hematocrit : Measurement of the sample's conductivity

1.2.2 Calibration procedure

tHb and SO_2 are calibrated when the instrument is calibrated. Ambient air and a zero point solution are used to calibrate oxygen. The remaining parameters are calibrated with the help of two solutions, which are mixed in various ratios. Gas containers are not used. The use of at least two calibration points for each measurement variable and constant internal monitoring of the calibrations ensures the accuracy and precision of the measurement values.

1.3 Measurement evaluation

The validity of the test results from the Roche OMNI C must be carefully examined by a clinical-medical specialist who will take the patient's clinical condition into consideration before any clinical decisions are reached based on the test results.

To ensure the quality of the measurement results, a quality control must be performed on 3 levels (low, normal, high) at least once daily, or more frequently depending on local regulations, after each electrode exchange and after the startup of the instrument (for detailed information see chapter 5 "Quality Control").

1.4 Safety instructions for specific dangers

1.4.1 Handling samples

Respect the necessary hygienic regulations when handling samples because samples may contain dangerous viruses.

For more detailed information, please see chapter 4, "Measurement."

1.4.2 Disposal of waste water, bottles, electrodes, and the instrument



Dispose waste water, bottles, electrodes and the instrument according to local and/or labour regulations (biologically contaminated—hazardous waste!)

1.4.3 Decontamination

The purpose of this procedure is to minimize risk when handling items that were in contact with biological samples.

Roche recommends following a decontamination procedure in addition to regulations specific to the laboratory.

These decontamination procedures should be performed periodically to minimize the risk of infections (incl. hepatitis virus and HIV).



Always wear gloves!

For more detailed information about decontamination, please see chapter 6, "Maintenance."

1.5 Handling solutions

Store the OMNI C solutions according to the specified packaging requirements. The solutions should be adapted to the ambient temperature before use.

The shelf life of the solutions is limited.

Please read the bottle label and the packaging for the correct storage temperature and the maximum shelf life.



CAUTION! DO NOT FREEZE!

If frozen, the solution's concentration may change and cause calibration errors!

Do not use damaged C3 fluid packs! Do not mix the individual components!

1.6 Handling electrodes

Store the electrodes according to the packaging specifications.

The shelf life of the electrodes is limited.

Please see the electrode label and the packaging for the correct storage temperature and the maximum shelf life.

TIP: *IMPORTANT! Installation note for the PCO₂ electrode*

Insert the electrode into the measuring chamber within 5 minutes of opening the ALU-PE packaging.

A special protective gas atmosphere designed to condition the PCO₂ electrode during storage is found inside the ALU-PE packaging.

This gas atmosphere ensures immediate potential stability during insertion of the electrode into the measurement chamber and/or immediate readiness for measuring after the 2 point calibration is completed.

If more than 5 minutes elapse after opening the ALU-PE packaging, the level of gas conditioning could be lost and the time required for the first-time calibration could be increased.

1.7 System description

1.7.1 Visual identification

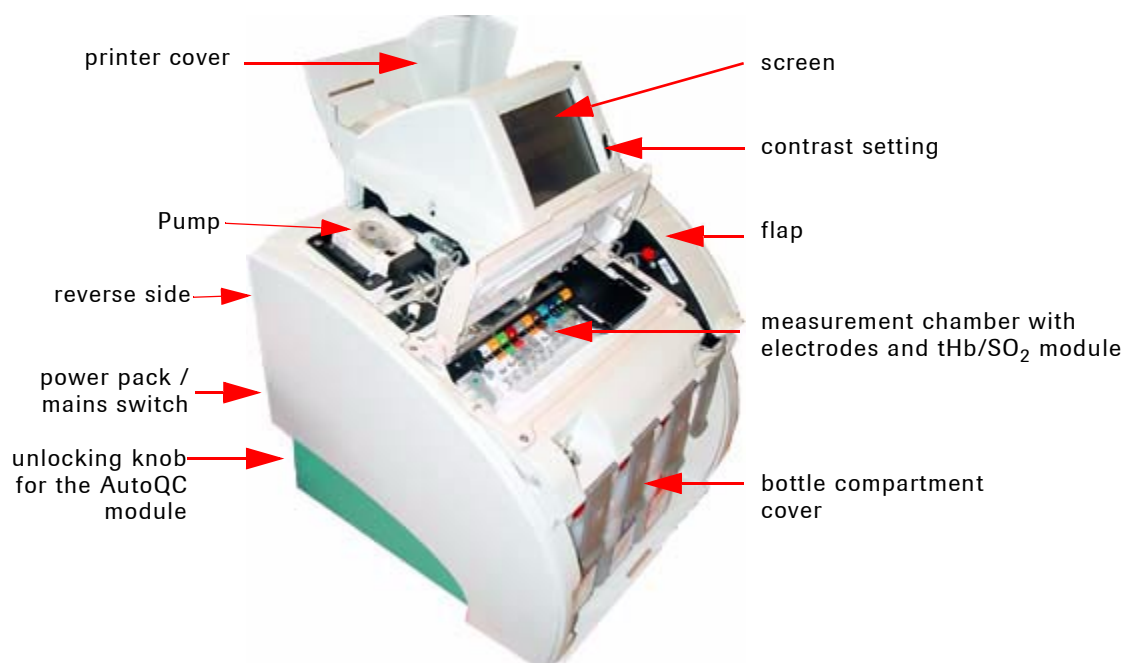


Fig. 2

1.7.2 Screen

All information (results, error messages, warnings, etc.) is displayed on the screen. The screen consists of a 5.7" colour LCD that is covered with a touch-sensitive film ("touch screen").

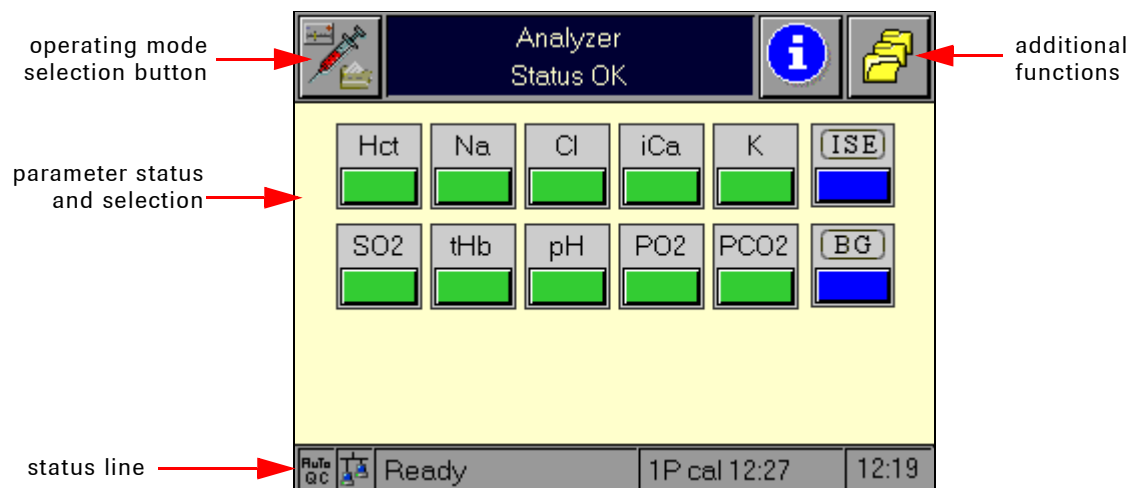


Fig. 3

Please refer to the respective chapters in these Instructions for Use as well as the Reference Manual for more detailed information about the operating modes.

Parameter – Display on the "Ready" screen

Depending on the settings and the status of the instrument, the parameter buttons may have the following appearance:

	Parameter activated and ready		Parameter not ready (not calibrated)*
	Parameter temporarily deactivated (but calibrated)		Parameter not ready (due to QC lock)
	Parameter activated with QC warning		Parameter not ready due to remote lock
	Parameter temporarily deactivated with QC warning		Parameter permanently deactivated (under "Setup")

* Pressing the parameter button produces a status report (see chapter 7, "Trouble shooting", section "Electrode status").

Parameter – notation of the measured, input, and calculated parameters¹**Measured parameters**

PO_2	Oxygen partial pressure
PCO_2	Carbon dioxide partial pressure
pH	Negative logarithm of the hydrogen ion activity
Na^+	Sodium concentration
K^+	Potassium concentration
Cl^-	Chloride concentration
Ca^{2+}	Calcium concentration
Hct	Hematocrit
tHb	Total hemoglobin concentration
SO_2	Functional oxygen saturation
Baro	Air pressure

Calculated parameters

H^+	Hydrogen ion concentration
$cHCO_3^-$	Bicarbonate concentration in plasma
$ctCO_2(P)$	Total CO_2 concentration in plasma
$ctCO_2(B)$	Total carbon dioxide concentration in blood
BE	Base deviation of blood
BE_{act}	Base deviation of blood at current oxygen saturation
BE_{ecf}	Base deviation of the extracellular fluid
BB	Buffer bases
ctO_2	Total oxygen concentration
pH_{st}	Standard pH value
$cHCO_3^-_{st}$	Standard bicarbonate concentration in plasma
PAO_2	Alveolar oxygen partial pressure
RI	Respiratory index
nCa^{2+}	Standardized ionized calcium (pH = 7.4)
Qs/Qt	Shunt—quotient between both oxygen concentration differences
Qt	Difference of oxygen concentration between alveolar and mixed venous blood
$P50 (c)$	Oxygen partial pressure at 50% oxygen saturation calculated with SO_2 as measurement value

1. Details and calculation, see Reference Manual

SO ₂ (c)	Functional oxygen saturation calculated with <i>P</i> 50 as input value
AaDO ₂	Alveolar-arterial oxygen partial pressure
a/AO ₂	Alveolar-arterial oxygen partial pressure ratio
avDO ₂	Arterial-venous oxygen level difference
AG	Anion gap
MCHC	Middle corpuscular hemoglobin concentration
Osm	Osmolality
OER	Oxygen extraction ratio
Hct(c)	Hct calculated from tHb
P/F index	PaO ₂ /FIO ₂ ratio

Calculated parameters at the patient's temperature

PAO ₂ ^t	Alveolar oxygen partial pressure at patient's temperature
RI ^t	Respiratory index at patient's temperature
AaDO ₂ ^t	Alveolar-arterial oxygen partial pressure at patient's temperature
a/AO ₂ ^t	Alveolar-arterial oxygen partial pressure ratio at patient's temperature
pH ^t	pH at patient's temperature
PCO ₂ ^t	PCO ₂ at patient's temperature
PO ₂ ^t	PO ₂ at patient's temperature
H ⁺ ^t	Hydrogen concentration at patient's temperature

Input parameters

<i>P</i> 50	Oxygen partial pressure at 50% oxygen saturation
RI	Gas exchange quotient
FIO ₂	Proportion of inspiratory oxygen
tHb	Total hemoglobine
Temperature	Patient temperature

Additional

Operator ID	Sample type	Blood type
Specimen ID	Puncture site	ALLEN test
A/F (adult/fetal)	Pat ID	Last name
First name	Middle initials	Date of birth
Gender	Pract. Pat ID	Height
Weight		

Input parameters—patient information

Insurance code	Suffix	Title
Maiden name	Color of skin	Address
Phone no.	Diagnosis	Medication
Diet	Admission date	Admission time
Discharge date	Discharge time	Admission status
Location	Diagnose code	Relig. denom.
Marital status	Isolation status	Patient language
Hospital service (KH service)	Hospital institute	Dosage cat.
Remark		

Input values—measurement information

Physician	Remark	Acceptor
Date drawn	Time drawn	Place drawn
Danger code	Clinic info	Container
24 hr. urine	Ventilation mode	VT
MV	PIP	Ti
Te	SRATE	ARATE
PEEP	MAP	Flow rate

Buttons



return to the highest level of the operating mode "Analyzer"



operating mode "Analyzer"



operating mode "Setup"



operating mode "Database"



additional functions



move one line up / down



page to the left / right, additional selection possibilities



select the marked entry



move one level up / back



activate / deactivate



confirm



cancel



go to additional views



print



add



remove



password



data input



details



start

1.7.3 *Printer*

The low-noise 2" thermal printer with integrated paper cutter for roll paper is located underneath the printer cover.

1.7.4 *Measurement chamber*

The measurement chamber with the electrodes and the tHb/SO₂ module are located underneath the instrument cover.

The electrodes are flow-through electrodes with a visible sample channel.

The tHb / SO₂-module is an optical sensor module for determining the levels of total hemoglobin (tHb) and oxygen saturation (SO₂) in whole blood.

1.7.5 *Pump*

A peristaltic pump transports the sample and the operating fluids inside the instrument.

1.7.6 *Flap*

When opening the flap, notice two definitive locking positions:

- Flap position 1 (half opened) – Syringe mode—for syringes and ampoules
- Flap position 2 (completely opened) – Capillary mode—for capillaries and microsamplers

1.7.7 *Bottle compartment*

The calibration solutions and the waste container are located behind the bottle compartment cover.

1.7.8 *Power supply*

This unit contains the mains power switch and the mains power connector.

Position of the mains switch



Fig. 4

1.7.9 Reverse side

Interface

Only data processing units manufactured according to the standards IEC 950 (UL1950) may be attached to the interface connections!

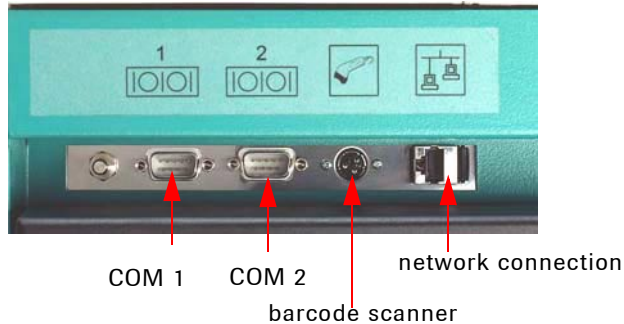


Fig. 5

- COM 1* RS 232 interface
- COM 2* RS 232 interface
- Barcode PS/2 DIN—6p jack
- Network 10 BaseT Ethernet (RJ45)

***TIP:** *Always use a filter adapter when using the serial interface. Please order this part from your customer service representative!*

COM 1

This interface can be assigned to a ticket printer and Host FMT.

For an exact description of the assignment, see the section "Settings > Interfaces > COM 1" in chapter 3, "Operating modes," of the Reference Manual.

COM 2

This interface can be assigned as serial interface to ASTM.

For an exact description of the assignment, see the section "Settings > Interfaces > COM 2" in chapter 3, "Operating modes," of the Reference Manual.

Barcode scanner



Fig. 6

- Scanning of solution data (type, batch number, date of expiry, current composition, etc.)
- Scanning of electrode data (type, batch number, date of expiry)
- Scanning of patient or user identity
- Scanning of QC data (QC material, batch number, basis, date of expiry, target values, etc.)
- Scanning of desired alphanumeric code

IMPORTANT: *Press the button on the underside to activate the scanner! A beeping sound and a brief illumination of the LED on the upper side indicate the successful scanning of the barcode.*

Warning and identification labels

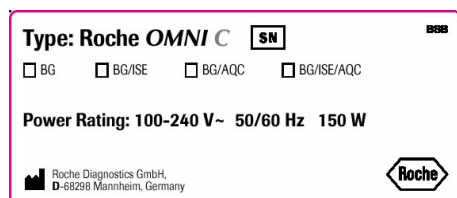


Fig. 7

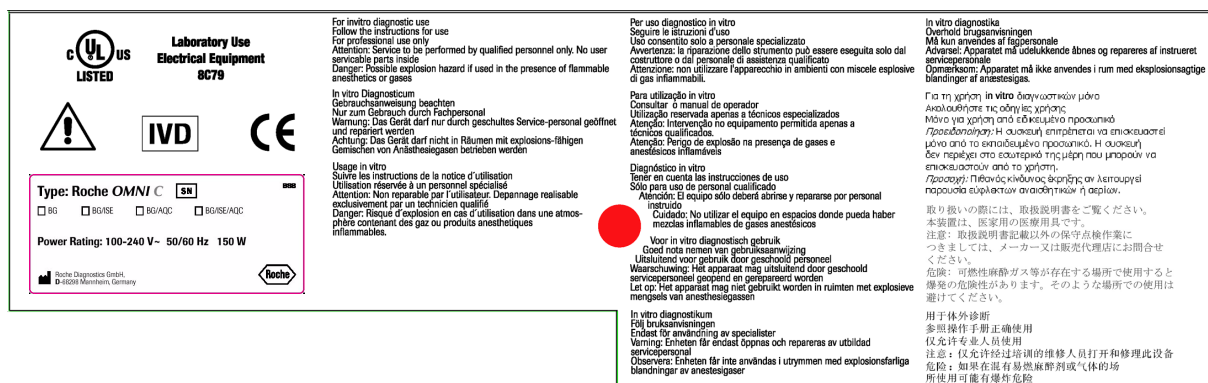


Fig. 8

1.8 Installation

1.8.1 Installation

Location

For best results, choose a suitable, level location that is not subject to direct sunlight for the device.

When installing an instrument that was stored in a cool room or was transported at low temperatures, be aware that condensation may have formed and could cause disturbances to the instrument. Be sure that the instrument is climatized for at least one hour at room temperature before beginning operation.

The following conditions must be fulfilled:

- Ambient temperature: + 15 °C to + 33 °C
- Avoid direct sunlight, vibration and strong electromagnetic fields (electric motors, transformers, X-ray equipment, cellular phones...).
- Use a stable and level work surface (max. 1° incline with bottles installed).
- Relative humidity: 20 to 95 % (at $\geq +15$ °C, to ≤ 31 °C)
20 to 90 % (at $> +31$ °C, to $\leq +33$ °C)
- Allow sufficient free space around the instrument for air circulation and the electrical connections.
- Check for the correct voltage: 100 to 240 VAC ($\pm 10\%$)

After setting up the Roche OMNI C analyzer at a location that meets the necessary conditions, execute the following steps to ensure the instrument is ready for operation:

- First check the instrument and the accessories for completeness and damage. The completeness of the delivery can be checked through comparison with the delivery packing slip.

If anything is missing, please inform your Roche representative immediately.

If the delivery has suffered damage despite careful packing, inform the transportation company immediately. Please retain the packaging material and products as evidence for the damage claim.

Accessories

The following parts are delivered as standard equipment with the Roche OMNI C:

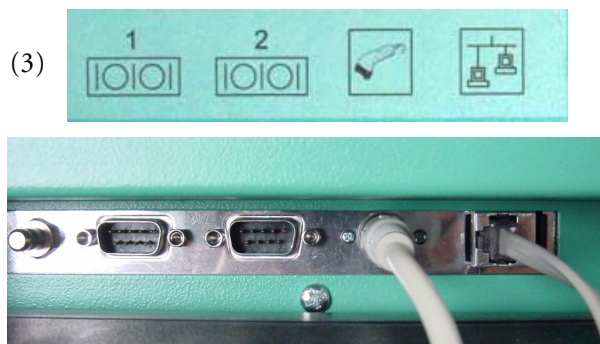
1 barcode scanner	1 shutdown kit
2 power cord	1 micro electrode dummy
2 pump tubes	2 fill port holders
1 sample drip tray	2 needles
1 paper roll	2 MCon

1. Attach power cord and barcode scanner

- Plug the power cord into the power supply (Fig. 9/1).
Connect the barcode scanner and, if necessary, the network cable (Fig. 9/2) to the respective interface(s) (Fig. 9/3) on the reverse side of the Roche OMNI C.



(1)



(2)

Fig. 9

- Open the bottle compartment cover and the docking mechanism.



docking mechanism

Fig. 10

- If available (optional equipment), install the AutoQC module.

2. Installing the AutoQC module (Automatic Quality Control Module)

IMPORTANT: Attempt to install and operate an AutoQC module only if the instrument is prepared for use with the AutoQC module. The valves V12 and V13 must be present in the bottle compartment (see Fig. 11)!



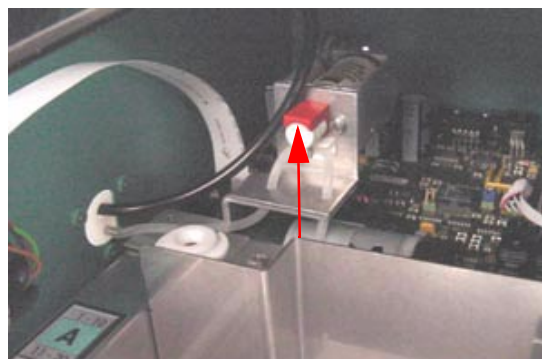
Fig. 11

IMPORTANT: Check to be sure that the power cord is connected to the power supply. After engaging the AutoQC module, it will no longer be possible to connect the cord to the power supply!

- Open the AutoQC cover and remove the transport safety band and both safety screws (see Fig. 12/1).
TIP: The safety screws are intended to fix the longitudinal and transversal slides and should only be re-inserted whenever the AutoQC module will be transported.
- Remove upward thered, the red plastic relief clamp from the AQC valve V17, which is located toward the back of the AQC unit on the inside (see Fig. 12/2).



(1)



(2)

Fig. 12

- On the right side of the Roche OMNI C, remove the gray plastic cover from the AutoQC docking port. Close the AutoQC cover and push the AutoQC module into the tracks on the Roche OMNI C until it locks into place.

The module's docking part will slide into the opening on the side wall on the Roche OMNI C and lock into place.

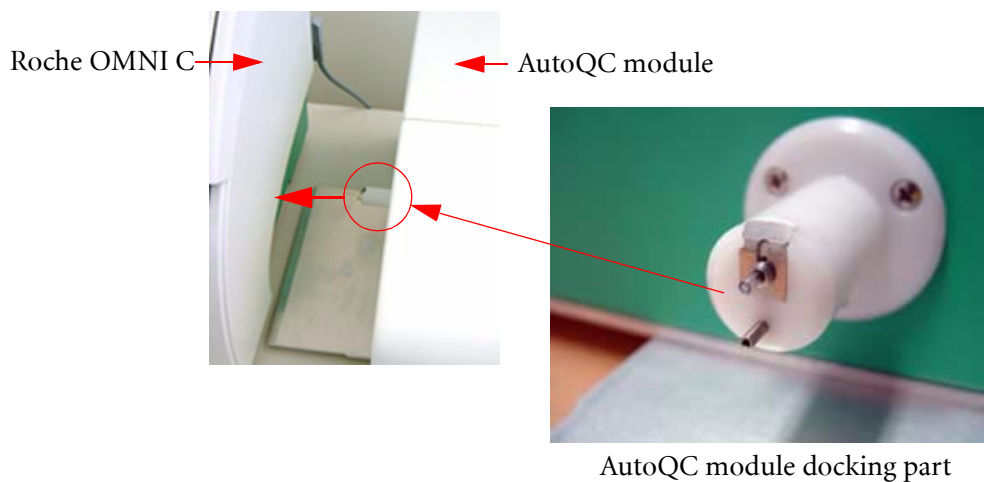


Fig. 13

- Connect both tube ends in the bottle compartment to the docking part according to Fig. 14.

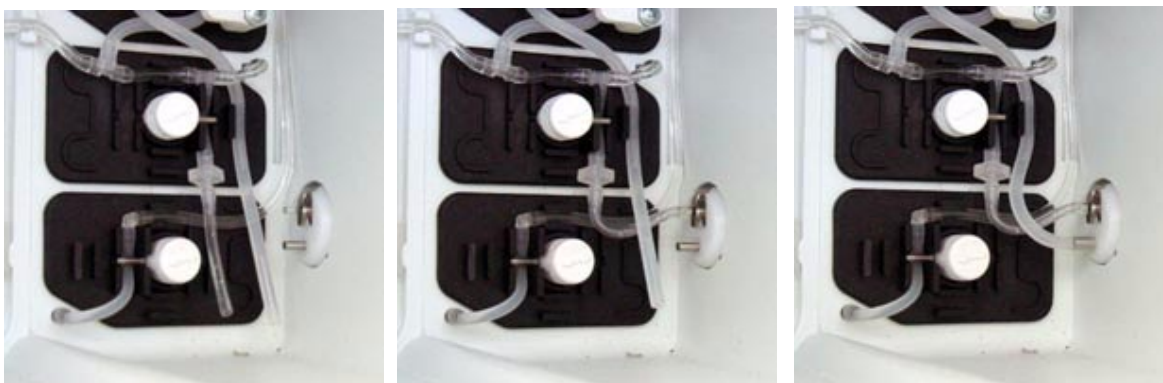


Fig. 14

- Connect the cable of the AutoQC module to the jack on the reverse side of the instrument.



Fig. 15

3. Switch on

- Switch the instrument on and wait until the program has loaded completely and has started. The instrument is in the "System stop" mode. Before beginning the start up procedures, you must select the language with which the instrument will be operated, set the date and time, check the barometer value and if the AutoQC module is activated.

4. Select language



and press **"Instrument > Language"**

- Select the language and confirm your selection with .
- Please see chapter 3, "Operating Modes", section "Setup" in the Reference Manual for an exact description.

5. Setting the date and time



and press **"Times & intervals > Date/Time"**

- Please see chapter 3, "Operating Modes", section "Setup" in the Reference Manual for an exact description.

6. Checking the barometer value



and **"System > Test > Control Sensors > Barosensor"**

- If the barometer value deviates by more than ± 2 mmHg from the value indicated by a precision barometer, it will be necessary for customer service to calibrate your barometer!

7. Checking the AutoQC module



and **"Instrument > AutoQC"**

- If the AutoQC module is not activated, press .
Changes will be accepted after reboot.
Press "Yes".

8. Installation

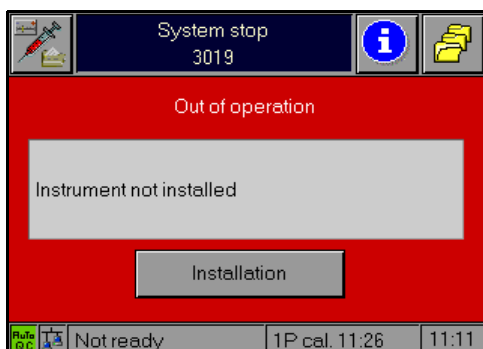


Fig. 16

- Press the "Installation" button and then continue by following the instructions on the screen!

TIP: Confirm every step by pressing the  button!

9. Check tubes at V2 and V9

- Check the bottle compartment's back wall to make sure that the air mixture tube (valve V2) and the ventilation tube (valve V9) are in the guides (see Fig. 17).

air mixture valve tube V2

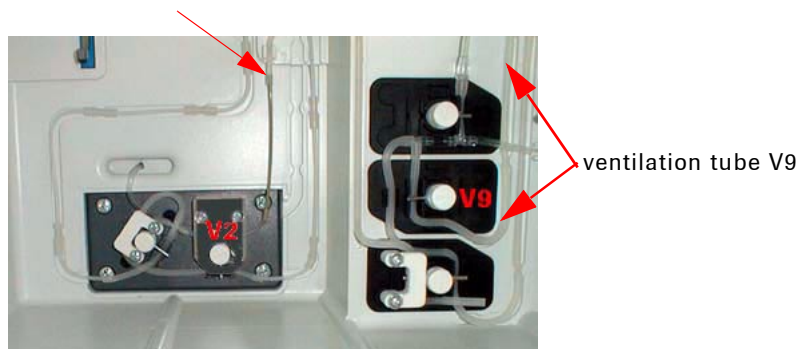


Fig. 17

10. Insert FMS tubes

- Slide the feed tube of the C1 solution under the tube clip (valve V1).
- Slide the feed tube of the C2 solution under the tube clip (valve V2) (see Fig. 18). Both of these valves are located on the back wall of the bottle compartment.

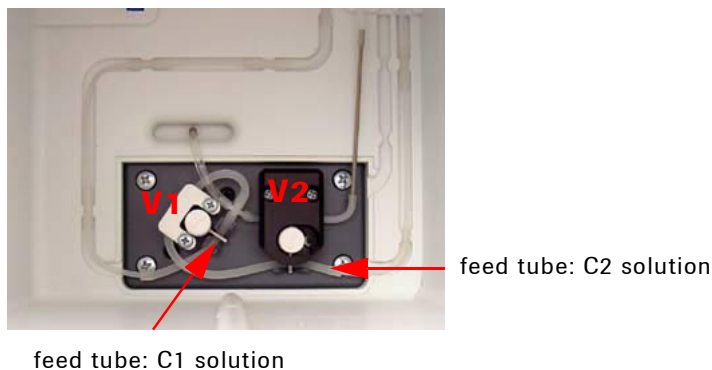


Fig. 18

11. AutoQC module (option)

- Open the cover of the AutoQC module.
- Insert the AutoQC ampoule block.
- Close the cover of the AutoQC module.
- Perform the mat assignments and program the AutoQC times. Please see chapter 5, "Quality Control"!

12. Attach pump tube

- Open the instrument cover.
- Open the peristaltic pump's clear plastic cover (tension lever). Push the linear bracket (white plastic part) upwards (Fig. 19).
- Place the tube around the rolling wheel.
- Close the clear plastic cover (tension lever). The tubing holder is then pressed into the sealer.

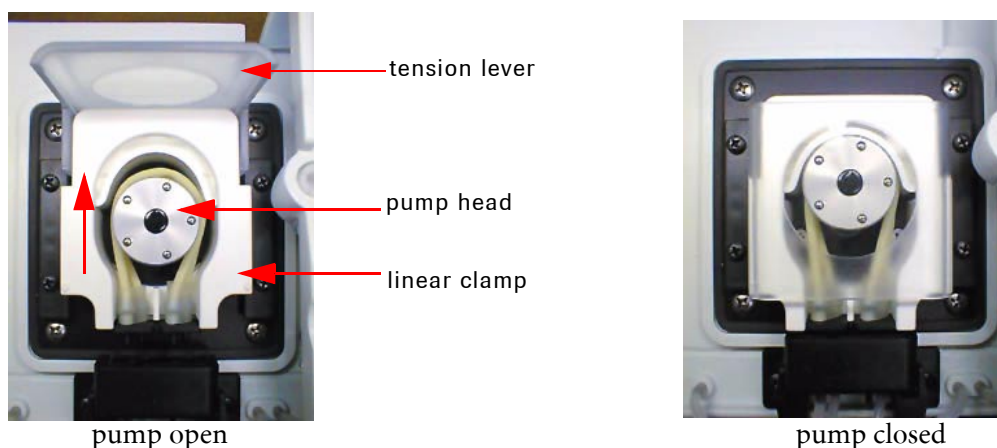


Fig. 19

13. Insert needle and fill port holder

- Open the flap to the labelled capillary position (completely open position).
- Insert the needle to the left into the sealing piece and then push the needle carefully down until it clicks into place.

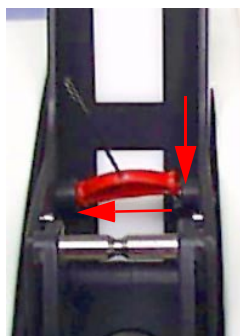
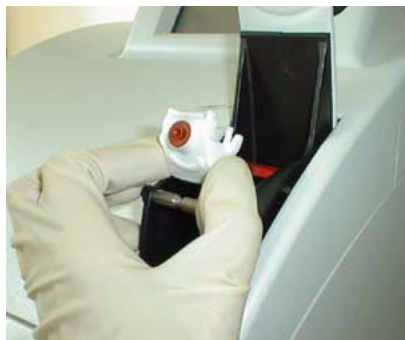


Fig. 20

- Rotate the fill port holder so that the underside shows on the top (see Fig. 21/1) and then push this over the needle (see Fig. 21/2).
- **CAUTION:** do not bend the needle when pushing it up!
- Snap the fill port holder evenly onto the axis (see Fig. 21/3).



(1)



(2)



(3)

Fig. 21

- Close the flap.

14. Insertion of printer paper

TIP: The printer paper is heat sensitive on one side only. Please make sure that you insert the paper roll correctly.

- Open the printer cover.
- Place the new paper roll into the holder.

- Make sure that the printer lever is in the "down" position (see Fig. 22).

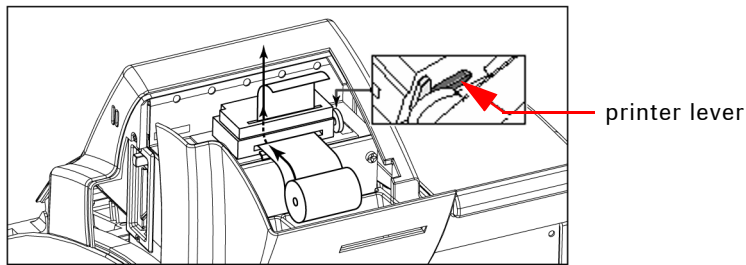


Fig. 22

- Cut off, at a right angle, the start of the paper.
- Feed in the start of the paper according to the sticker on the inside of the printer cover. The paper is automatically pulled into the printer.
- Close the printer cover and feed the paper outward through the slit in the printer cover.

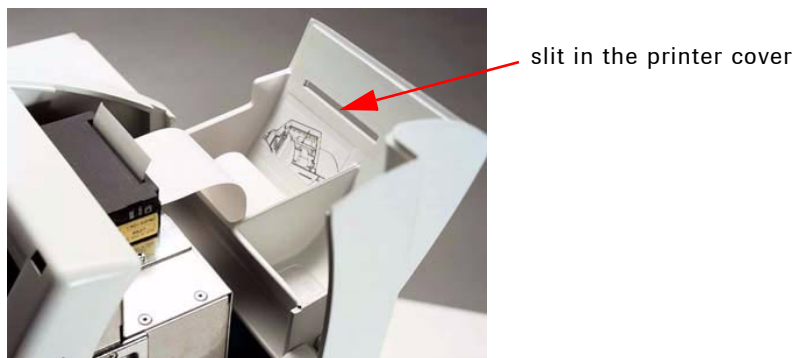


Fig. 23

15. Insertion of bottles

TIP: To avoid splashing the C1 and C2 calibration solutions, deaerate the bottles at about 3000 m above sea level or higher before inserting them.

- To do this, place the bottle tool on the screw cap of the C1 or C2 (Fig. 24/1).
- Press the grips together and press the transparent disk downward (Fig. 24/2).
- Rotate the transparent disk in the clockwise direction. Stop when you notice (after a short distance) resistance (Fig. 24/3).

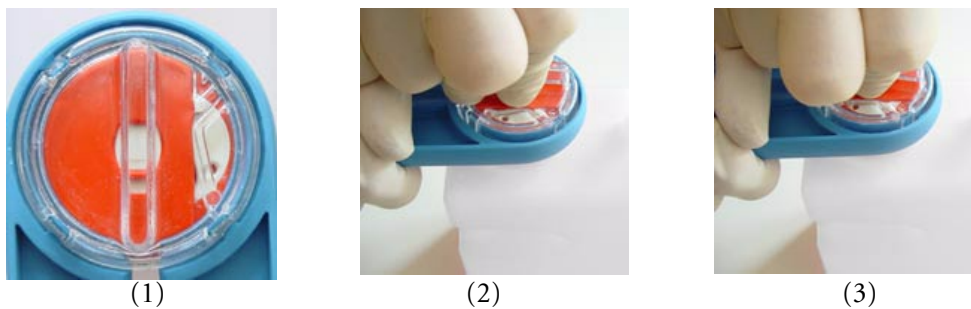


Fig. 24

- Scan the barcodes on the bottles of C1 calibration solution 1, C2 calibration solution 2 and the C3 fluid pack (exception: the waste water bottle, which does not have a barcode) (see Fig. 25/1).
- The Roche OMNI C recognizes the correct solution and checks the expiration date. On the screen, the respective bottle starts blinking. If the bottle has passed the expiration date, the screen displays a warning.

Confirm with the  button.



Remove rubber sealings from C3 Fluid Pack before inserting it!

- Insert the bottle completely into the appropriate position, following the instructions on the docking mechanism (see Fig. 25/2). The bottles are opened automatically.
 - Close the docking mechanism.
- Check the positions of the bottles by matching the labels on the docking mechanisms to the labels on the bottles (see Fig. 25/3).



(1)



(2)



(3)

Fig. 25

- Close the bottle compartment cover.

16. Insert electrodes

- Open the measuring chamber cover.
- Open locking lever.
- Follow the instructions on the screen.

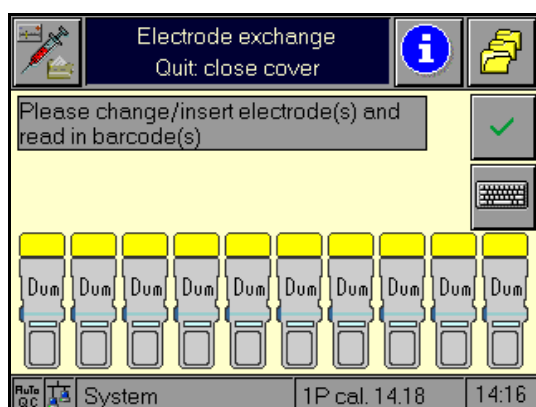


Fig. 26



Make sure that no air bubbles have formed in the inner electrolytes of the electrodes (see Fig. 27). If there are air bubbles between the contact pin and the membrane, there will not be effective electrical conduction. Result: calibration and measurement errors!

- If necessary, remove air bubbles by holding the electrode vertically and by tapping lightly with your fingernail against the electrode body (see Fig. 27)..



free of air bubbles!



Fig. 27

- Insert the electrodes, beginning at the right and proceeding left according to the colour code.
- Push all electrodes slightly to the right so that they are lined up together without gaps.

17. Insertion of the reference electrode

- Insert the new reference electrode.

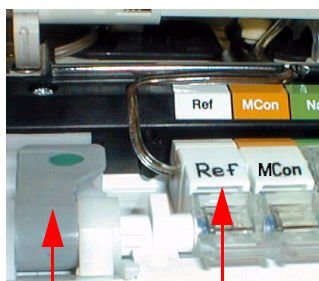


Fig. 28

- Place the tube into the tube guide slot (see Fig. 29).



Be sure that the tube lies precisely in the guide slot. Otherwise it may be pinched, thereby preventing suction of the reference solution. Result: calibration and measurement errors!



locking lever reference electrode
(1)



(2)

Fig. 29

- Affix the white plug at the end of the reference electrode tube (see Fig. 30).
IMPORTANT: push the plug in completely.

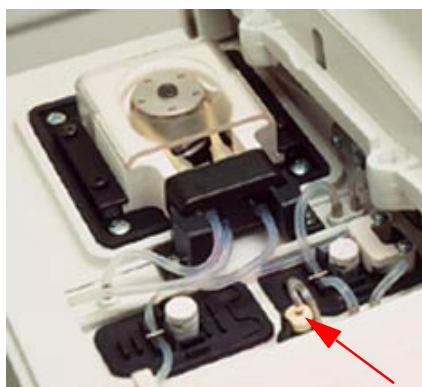


Fig. 30

- Close the locking lever.
- Inspect the electrical contact of the electrodes by checking if they fit tightly. The correct position of the various electrodes is easy to recognize by looking at the colours of the contact strips or at their labels.



Fig. 31

- Scan the barcodes located on the inner packaging of each electrode or enter the barcodes manually with the help of  .

TIP: *Always save the inside packaging materials! Whenever the Roche OMNI C is taken out of service and then brought back into service, the barcodes of the remaining functional electrodes must be scanned again!*



Fig. 32

- The corresponding electrode starts blinking on the screen. Confirm with the  button.
- Close the measuring chamber and then the instrument cover.

18. Begin installation routines

- Press: 
- All solutions are aspirated and the system is calibrated; this may take longer than the respective actions during operation.
- Installation is complete.

If an error occurs during one of the steps, a system stop is displayed, but the instrument has been brought "into operation."

Please see chapter 7, "Trouble shooting", for instructions on clearing the system stop.

19. Quality control

- You must define the material before executing a quality control measurement.
- For instructions, please see chapter 5, "Quality control."
- Perform a quality control on all 3 levels.
- Make sure that the results agree with the target values (see chapter 5, "Quality control").

1.9 Shutdown

1.9.1 Less than 24 hours

If the Roche OMNI C will be needed within the next 24 hours, press:



and **"System > Tools > Software shutdown"**

and switch the instrument OFF.

1.9.2 Longer than 24 hours

If the Roche OMNI C will be shut down for longer than 24 hours, perform the following procedure.

TIP: *Before shutting down the instrument, backup the data to a PCMCIA card or an interface (see chapter 8, "Operating modes", section "Database").*



TIP: *Roche Diagnostics recommends decontaminating all surfaces and tubing before shutting down the instrument. Please see chapter 6, "Maintenance", section "Decontamination", for a detailed description!*

While in the "Analyzer" operating mode, press:



and **"System > Tools > Shutdown"**

Follow the instructions on the screen.

Confirm every step with  !

1. Remove bottles

- Open the bottle compartment cover and remove bottles C1, C2, C3.

2. Remove the V2 and V9 tube ends from the guides

- Remove the air mixture valve tube (valve V2) from the guide.

- Remove the ventilation tube (valve V9) from the guide.

air mixture valve tube V2

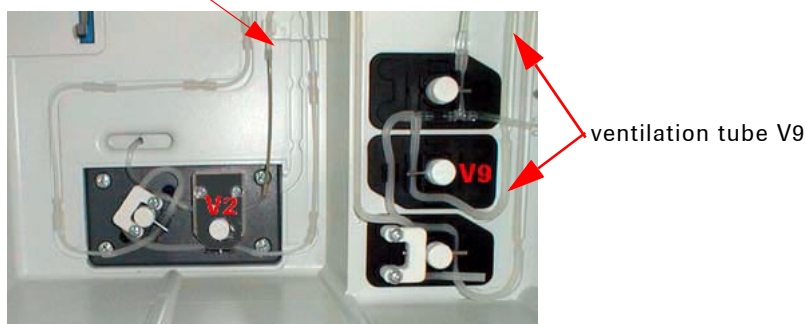


Fig. 33

- Place both ends of the tube onto an absorbent pad, such as a paper towel or gauze (see Fig. 34).

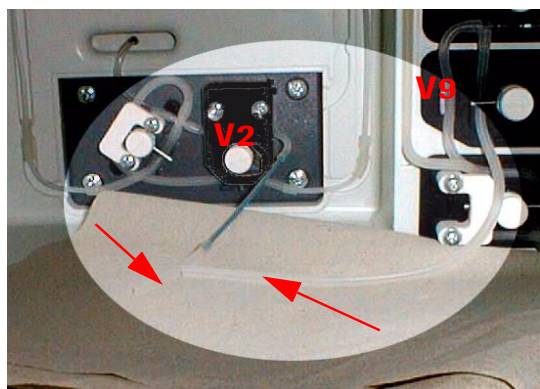


Fig. 34

3. Insert the shutdown kit and connect it

- Fill the shutdown kit about halfway with distilled water.
- Insert the shutdown kit into space C3.
- Connect the tubes of the set with the connectors from C1 and C2.



Fig. 35



- Begin the tube washing procedure by pressing the  button.

4. Remove the shutdown kit.

- Remove the shutdown kit.
TIP: Remove the remaining fluid from the tubes of the shutdown kit by briefly holding the tubes vertically, allowing the fluid to run back into the container.
- Start the procedure for emptying the tubes by pressing the  button.

5. Remove the waste water bottle

- Then remove the waste water bottle (W waste container).

6. Return the V2 and V9 tube ends to the guides

- Return the air mixture valve tube (valve V2) to the guides.
- Return the ventilation tube (valve V9) to the guides (see Fig. 36).

Air mixture valve tube V2

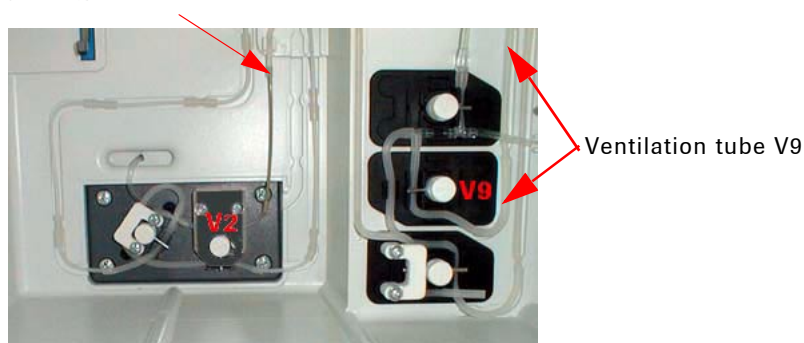


Fig. 36

- Close the docking mechanisms.

7. Remove the pump tube

- Open the instrument cover.
- Open the peristaltic pump's clear plastic cover (tension lever). Push the linear clamp (white plastic piece) upwards (see Fig. 37).

- You can now remove the entire tube set (tube holder with tubes) (see Fig. 37).

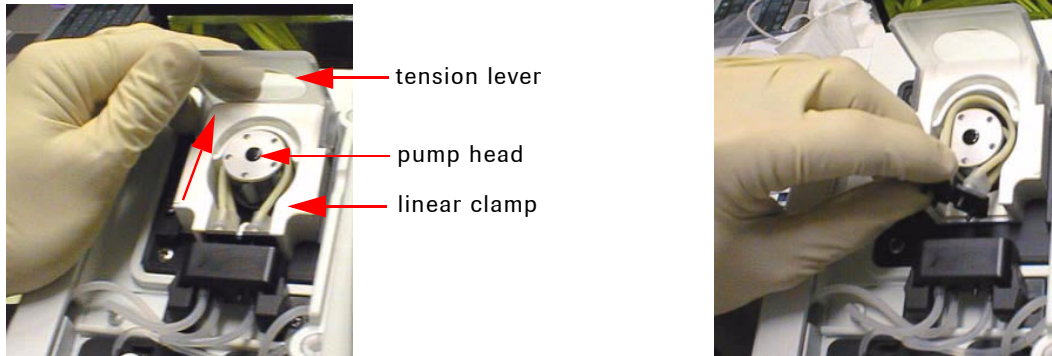
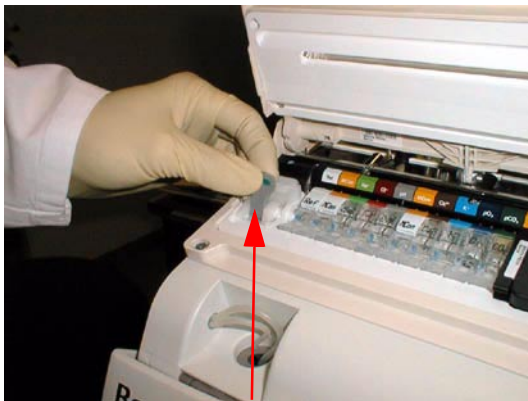


Fig. 37

- Close the tension lever (clear plastic cover).

8. Remove the electrodes

- Open the measuring chamber cover.
- Open the locking lever.



locking lever

Fig. 38

- Remove the electrodes.
- Close the locking lever and the measurement chamber cover.

9. Remove needle and fill port

- Open the flap to the labelled capillary position (completely open position).
- Rotate the fill port holder in the direction of the arrow (see the marking on the fill port holder). It will come out of the axis and snap out of place (see Fig. 39/1)
CAUTION: Do not bend the needle!
- Carefully remove the fill port holder from the needle (see Fig. 39/2).
Remove the needle.

- Push the needle to the left and into the sealer. Then carefully pull it upward (see Fig. 39/3).

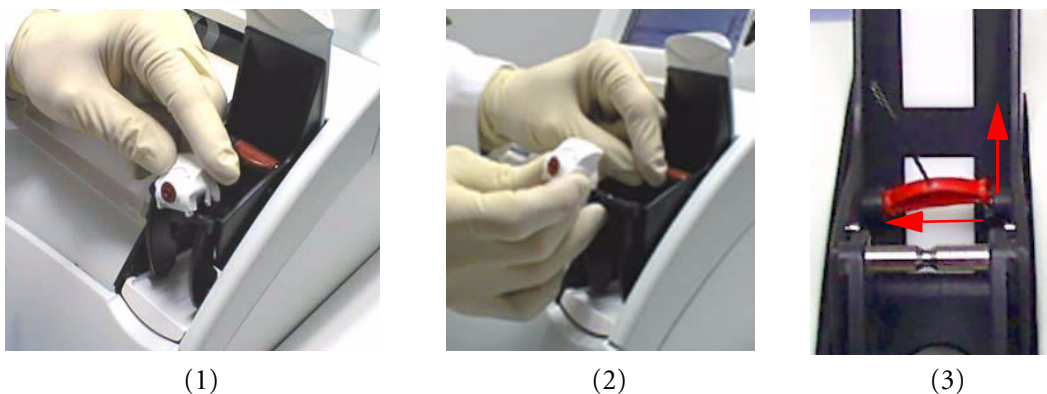


Fig. 39

- Close the flap.

10. Remove the printer paper

- Open the printer cover.
- Pull out the printer paper to the rear and remove it.
- Close the printer cover.

11. Remove the tube under V1 and V2

- Slide the feed tube of the C1 solution under the tube clip (valve V1) and out.
- Slide the feed tube of the C2 solution under the tube clip (valve V2) and out.

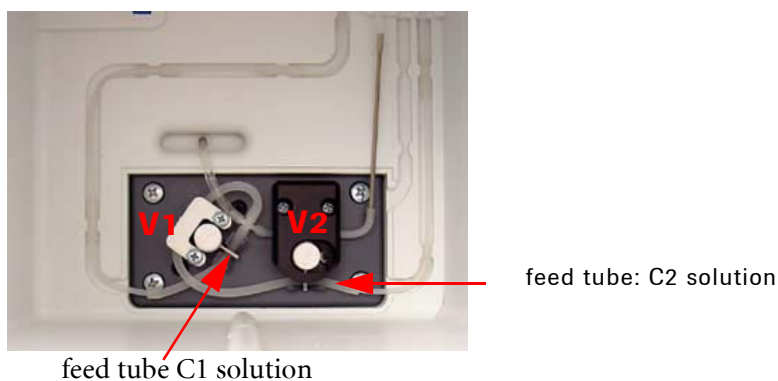


Fig. 40

- Pressure is removed from the tubes.

If available (option):

12. Shutting down the AutoQC module

- Open the cover and remove the AutoQC ampoule block.
- The carriage in the AutoQC module moves to the service position.
- Close all covers.

TIP: *After successfully shutting down the instrument, it will be in the "System stop" mode (shut down). Only a renewed installation procedure can alter this status.*

- Switch the instrument OFF.
- Shut down is complete.

13. Uninstall the AutoQC module

- Pull the cable of the AutoQC module from the jack on the reverse side of the instrument (see Fig. 41).

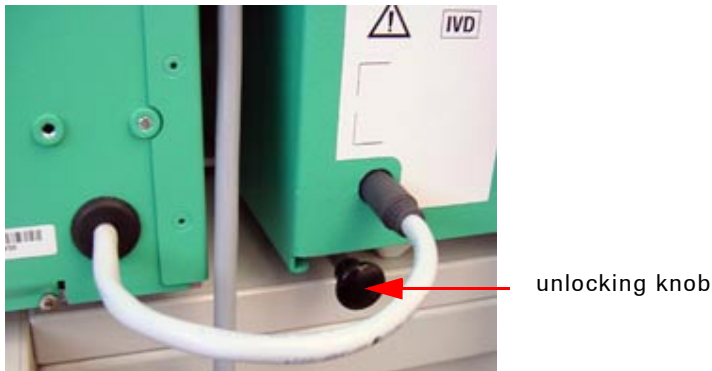


Fig. 41

- Remove both tube ends in the bottle compartment from the docking part.

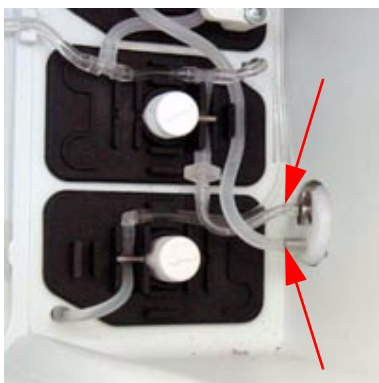


Fig. 42

- Unlock the AutoQC module by pulling the unlocking knob (see Fig. 41) on the reverse side of the instrument and remove the AutoQC module from the tracks on the Roche OMNI C.

- Insert the red plastic relief clamp for the AQC valve V17.

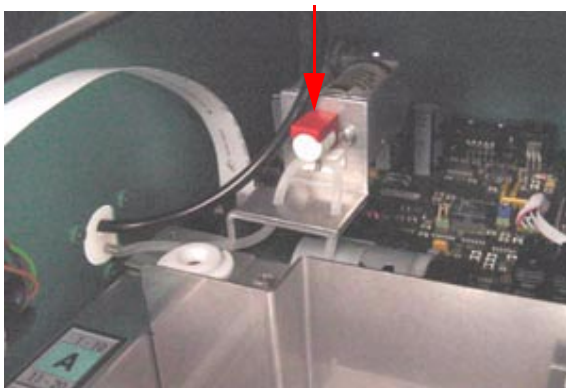


Fig. 43

- If you plan to transport the instrument, be sure to unplug the power cord, the scanner, and the network cable. Then install the transport safety device for the AutoQC module.



Fig. 44

- Use the original packaging when transporting the instrument!

2 Specifications

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2 Specifications

2.1 Measured parameters

	specified for:	Specified range	Precision ^{1), 2)} (within-run)	Precision ^{1), 2)} (day-day)	Accuracy ¹⁾	
PO ₂	B	0 - < 60 mmHg	SD < 4.0 mmHg	SD < 6.0 mmHg	< ± 8.0 mmHg	
		60 - 140 mmHg	SD < 2.0 mmHg	SD < 3.0 mmHg	± 4.0 mmHg	
		> 140 - 500 mmHg	SD < (2% - 0.8 mmHg)	SD < (4% - 2.6 mmHg)	< ± (6% - 4.4 mmHg)	
		> 500 - 800 mmHg	SD < (4% - 11.8 mmHg)	SD < (8% - 22.6 mmHg)	< ± (12% - 34.4 mmHg)	
	Q	0 - > 7.998 kPa	SD < 0.533 kPa	SD > 0.800 kPa	< ± 1.066 kPa	
		7.998 - 18.662 kPa	SD < 0.267 kPa	SD < 0.400 kPa	± 0.533 kPa	
		> 18.662 - 66.650 kPa	SD < (2% - 0.107 kPa)	SD < (4% - 0.347 kPa)	< ± (6% - 0.587 kPa)	
		> 66.650 - 106.640 kPa	SD < (4% - 1.573 kPa)	SD < (8% - 3.013 kPa)	< ± (12% - 4.586 kPa)	
PCO ₂	B/Q	4 - < 15 mmHg	SD < 2 mmHg	SD < 3 mmHg	± 4 mmHg	
		15 - 80 mmHg	SD < 1.5 mmHg	SD < 2.0 mmHg	± 2.5 mmHg	
		> 80 - 200 mmHg	SD < 4.5 mmHg	SD < 6 mmHg	± 8 mmHg	
		0.533 - < 2.00 kPa	SD < 0.267 kPa	SD < 0.400 kPa	± 0.533 kPa	
	pH	B/Q	2.00 - 10.664 kPa	SD < 0.200 kPa	SD < 0.267 kPa	± 0.333 kPa
			10.664 - 26.660 kPa	SD < 0.600 kPa	SD < 0.800 kPa	± 1.066 kPa
Na ⁺	B/S/A/D/Q	6.0 - < 6.8	SD < 0.020	SD < 0.035	± 0.06	
		6.8 - 7.6	SD < 0.008	SD < 0.015	± 0.02	
		> 7.6 - 8.0	SD < 0.015	SD < 0.030	± 0.04	
K ⁺	B/S/A/D/Q	20 - < 120 mmol/L	SD < 4.5 mmol/L	SD < 6 mmol/L	± 8 mmol/L	
		120 - 170 mmol/L	SD < 1.5 mmol/L	SD < 2.0 mmol/L	± 2.5 mmol/L	
		> 170 - 250 mmol/L	SD < 6 mmol/L	SD < 8 mmol/L	± 10 mmol/L	
Cl ⁻	B/S/A/D/Q	0.2 - < 3.0 mmol/L	SD < 0.15 mmol/L	SD < 0.35 mmol/L	± 0.5 mmol/L	
		3.0 - 6.0 mmol/L	SD < 0.06 mmol/L	SD < 0.15 mmol/L	± 0.2 mmol/L	
		> 6.0 - 20 mmol/L	SD < 0.4 mmol/L	SD < 1 mmol/L	± 1.4 mmol/L	
Ca ²⁺	B/S/A/D/Q	20 - < 70 mmol/L	SD < 3 mmol/L	SD < 4 mmol/L	± 8.0 mmol/L	
		70 - 130 mmol/L	SD < 1.5 mmol/L	SD < 2.0 mmol/L	± 4.0 mmol/L	
		> 130 - 250 mmol/L	SD < 4.5 mmol/L	SD < 6 mmol/L	± 12.0 mmol/L	
		0.1 - < 0.6 mmol/L	SD < 0.06 mmol/L	SD < 0.1 mmol/L	± 0.2 mmol/L	
		0.6 - 1.5 mmol/L	SD < 0.03 mmol/L	SD < 0.05 mmol/L	± 0.1 mmol/L	
		> 1.5 - 4.0 mmol/L	SD < 0.15 mmol/L	SD < 0.25 mmol/L	± 0.5 mmol/L	
		0.4008 - < 2.4048 mg/dL	SD < 0.2405 mg/dL	SD < 0.4008 mg/dL	± 0.8016 mg/dL	
		2.4048 - 6.0120 mg/dL	SD < 0.1202 mg/dL	SD < 0.2004 mg/dL	± 0.4008 mg/dL	
		> 6.0120 - 16.0320 mg/dL	SD < 0.6012 mg/dL	SD < 1.0020 mg/dL	± 2.0040 mg/dL	

	specified for:	Specified range	Precision ^{1), 2)} (within-run)	Precision ^{1), 2)} (day-day)	Accuracy ¹⁾
Hct	B/Q	10 - < 20%	SD < 3%	SD < 5%	± 6.0%
		20 - 60%	SD < 1.5%	SD < 2.5%	± 3.0%
		< 60 - 80%	SD < 3%	SD < 5 %	± 6.0%
		0.100 - < 0.200	SD < 0.030	SD < 0.050	± 0.060
tHb	B	0.200 - 0.600	SD < 0.015	SD < 0.025	± 0.030
		< 0.600 - 0.800	SD < 0.030	SD < 0.050	± 0.060
		3 - < 6 g/dL	SD < (3.0% + 0.27 g/dL)	SD < (3.3% + 0.30 g/dL)	< ± (-3.3% + 0.70 g/dL)
		6 - 18 g/dL	SD < 0.45 g/dL	SD < 0.5 g/dL	< ± 0.5 g/dL
		> 18 - 25 g/dL	SD < (2.1% + 0.06 g/dL)	SD < (2.1% + 0.11 g/dL)	< ± (7.1% - 0.78 g/dL)
		30.00 - < 60.00 g/L	SD < (3.0% + 2.70 g/L)	SD < (3.3% + 3.00 g/L)	< ± (-3.3% + 7.00 g/L)
		60.00- 180.00 g/L	SD < 4.50 g/L	SD < 5.00 g/L	< ± 5.00 g/L
		> 180.00- 250.00 g/L	SD < (2.1% + 0.60 g/L)	SD < (2.1% + 1.10 g/L)	< ± (7.1% - 7.80 g/L)
	Q	1.86 - < 3.72 mmol/L	SD < (3.0% + 0.17 mmol/L)	SD < (3.3% + 0.19 mmol/L)	< ± (-3.3% + 0.43 mmol/L)
		3.72 - 11.16 mmol/L	SD < 0.28 mmol/L	SD < 0.31 mmol/L	< ± 0.31 mmol/L
		> 11.16 - 15.51 mmol/L	SD < (2.1% + 0.04 mmol/L)	SD < (2.1% + 0.07 mmol/L)	< ± (7.1% - 0.48 mmol/L)
		3 - < 12 g/dL	SD < 0.36 g/dL	SD < 0.40 g/dL	< ± 0.36 g/dL
		12 - 25 g/dL	SD < 3.0%	SD < 3.3%	< ± 3.0%
		30.00 - < 120.00 g/L	SD < 3.60 g/L	SD < 4.00 g/L	< ± 3.60 g/L
		120.00 - 250.00 g/L	SD < 3.0%	SD < 3.3%	< ± 3.0%
		1.86 - < 7.44 mmol/L	SD < 0.22 mmol/L	SD < 0.25 mmol/L	< ± 0.22 mmol/L
		7.44 - 15.51 mmol/L	SD < 3.0%	SD < 3.3%	< ± 3.0%
SO₂	B	50 - < 60%	SD < (-5.0% + 4.0 %)	-----	< ± (-20% + 14%)
		60 - 100%	SD < 1.0%	-----	< ± 2.0%
	Q	50 - 100%	SD < 1.0%	SD < 1.1%	< ± 2.0%
Baro		300 - 800 mmHg	-----	-----	< 5.0 mmHg
		399.99-1066.64 mbar	-----	-----	6.67 mbar
		39.990-106.640 kPa	-----	-----	0.667 kPa

1) Accuracy and standard deviations: specified for the standard temperature range of 15 - 31 °C!

2) According to NCCLS within the specific range

3) When used within the range of 300...450 mmHg, the barosensor must be calibrated by customer service before initial start up

!

B whole blood

Adialysis solutions containing acetate

Sserum or plasma

Q ... aqueous QC material

D dialysis solutions containing bicarbonate

2.2 Default and input values

Parameter	Default value	Range (default values)	Range (input values)
tHb	15.0 g/dL 150.0 g/L 9.3 mmol/L	11.0 16.0 g/dL 110.0 160.0 g/L 6.8 9.9 mmol/L	1.0 26.0 g/dL 10.0 260.0 g/L 6.2 161.3 mmol/L
P_{50}	26.7 mmHg 3.56 kPa	15.0 40.0 mmHg 2.00 5.33 kPa	15.0 40.0 mmHg 2.00 5.33 kPa
FIO_2	0.21	0.1 1.0	0.1 1.0
RI	0.84	0.7 2.0	0.7 2.0
patient temperature	37.0 °C 98.6 °F	2.0 44.0 °C 35.6 111.0 °F	2.0 44.0 °C 35.6 111.0 °F

2.3 Sample throughput

Activated / installed electrodes	Typical sample throughput [samples/hours]	
	Syringe	Capillary
BG – tHb/SO ₂	30	30
BG – ISE – tHb/SO ₂	30	30

2.4 Sample volumes

Activated / installed electrodes	Typical sample volume [µl]	Typical withdrawal volumes [µl]	Volume limitation by the sample sensor [µl]
BG – ISE – tHb/SO ₂	60	90	68

2.5 Sample types

Whole blood, serum, plasma, dialysis solutions containing acetate and bicarbonate, QC material

2.6 *Calibrations*

Calibrations	Time intervals	Length (typical) [min]
Sys cal	every 24 hours (alternatively 8, 12 or 24 hours)	<15
1P cal	every 30 minutes (alternatively 1 hour)	<2
2P cal	every 12 hours (alternatively 4, 6, 8 or 12 hours)	<7
Warm-up phase	when turning ON ¹⁾	<25
Warm-up phase	power failure < 1 minute	<2
Electrode exchange	as needed	<27

¹⁾incl. calibration

2.7 Environmental parameters

2.7.1 Temperature / humidity / stability

Instrument

Operating conditions:

Ambient temperature	+15 °C to +33 °C
Relative humidity	20 - 95%, if $T \geq +15$ to $\leq +31$ °C 20 - 90%, if $T > 31 \leq 33$ °C
Measurement chamber temperature	37 °C $\pm$ 0.2 °C

Storage and transportation conditions:

Temperature	-20 °C to +50 °C
Humidity	up to 95% (not condensed)
Shock resistance	< 30 g

Electrodes

Operating conditions:

Operating temperature	+37 °C
Relative humidity	20 - 95%, if $T \geq +15 \leq +31$ °C 20 - 90%, if $T > 31 \leq 33$ °C

Storage conditions in original packaging:

Temperature	+15 °C to +30 °C
Humidity	20 to 85 % (not condensed)

Transportation conditions in original packaging:

Temperature	-5 °C to +40 °C over a period of 3 days
Humidity	20 - 80 % (not condensed) over a period of 3 days
Shock resistance	< 50 g

Solutions**Operating conditions:**

Ambient temperature	+15 °C to +33 °C
Relative humidity	20 - 95%, if $T \geq +15 \leq +31$ °C 20 - 90%, if $T > 31 \leq 33$ °C

Storage conditions in original packaging:

Temperature	+2 to +30 °C
Humidity	20 to 95 %

Transportation conditions in original packaging:

Temperature	+2 °C to +45 °C over a period of 7 days
Relative humidity	20 - 95%
Shock resistance	< 30 g

Stability during operation

Solutions	Description	with ambient temperature of 15 - 33 °C [weeks]
C1 calibration solution 1	Calibration solution	min. 4, up to 6 (depending on the remaining volume)
C2 calibration solution 2	Calibration solution	min. 4, up to 6 (depending on the remaining volume)
C3 fluid pack	Solution pack	8

QC-Material**Storage conditions in original packaging**

Temperature	COMBITROL TS	+2 bis +8 °C < 24 months
	AUTO-TROL TS	+2 bis +8 °C < 24 months

Transportation conditions in original packaging

Temperature	COMBITROL TS	< +28 °C max. 3 months
	AUTO-TROL TS	< +28 °C max. 3 months

Stability during operation

Temperature	COMBITROL TS	< +28 °C up to 3 months
	AUTO-TROL TS	< +28 °C up to 3 months (incl. up to one month on the AutoQC module)

2.8 Product data

2.8.1 Electrical data

Mains voltage range	100 to 240 VAC ($\pm 10\%$ permissible tolerance)
Frequency.....	50/60 Hz
Required power	150 W

2.8.2 Classification

Protection class	I
Overvoltage category	II
Contamination level	2

2.8.3 Dimensions

Instrument

Width	35.4 cm
Height	46.7 cm
Depth	41.0 cm

AutoQC module

Width	19.5 cm
Height closed.....	19.8 cm (open: 38.7 cm)
Depth	39.5 cm

2.8.4 Weight

Roche OMNI C (instrument)	about 17 kg (without calibration solutions!)
Roche OMNI C ready for shipment	about 23 kg
AutoQC module	5,9 kg (without ampoule mats)

2.9 Printer

Type.....thermal printer with integrated paper cutter
Resolution12 dots / mm
Full graphics576 dots / line
Printing speed8 mm / sec
Paper width58 mm
Paper lengthabout 30 m

2.10 Screen

Type.....integrated flat LCD screen
Format5.7 inch
Resolution.....320 x 240 pixel

2.11 Barcode scanner

Type.....MT 9060/4 Wedge PS2 hand-held scanner with integrat-
ed decoder
ManufacturerMarson Technology Co., LTD
Reading speedup to 45 scans/sec.
Resolution.....0.1 mm
Reading distanceup to 5 cm
Reading widthup to 9 cm
Preprogrammed code types:..... Full code 39 / code 39
EAN/UPC, Codabar
Interleaved 2 of 5
Code 11
EAN-13
UPC-A
Code 128
MSI / Plessey

3 Calibration

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3 Calibration

The Roche OMNI C employs a patented method that allows the simultaneous calibration of PCO_2 , pH, Na^+ , K^+ , Ca^{2+} and Cl^- electrodes while using only two calibration solutions (C1 calibration solution 1 and C2 calibration solution 2).

The chemical properties of the basis solutions and the concentration of their components make the system insensitive to environmental influences during storage and use.

3.1 Automatic calibrations

The following calibrations are automatically initiated and performed by the analyzer.

3.1.1 System calibration

Every 8, 12 or 24 hours (default) which includes the following:

- Cleaning with internal cleaning solution
- Automatic conditioning of the Na electrode (every 24 hours)
- Calibration of the mixing system
- 2 point calibration of all parameters

TIP: The user can set a permanent start time for the system calibration. This enables completion of calibration tasks while the Roche OMNI C is not in use or when the workload in the laboratory or station is smaller (see Reference Manual, chapter 8, "Operating modes", section "Setup").

3.1.2 2P calibration (2P cal)

This calibration is a 2 point calibration of all parameters.

Adjustable: 4, 6, 8, and 12 hours (standard).

3.1.3 1P calibration (1P cal)

This calibration is a 1 point calibration (incl. O_2) of all parameters.

Adjustable: every 30 minutes (standard), 1 hour.

3.1.4 Recalibration

This calibration is a 1-point calibration (without O_2) performed after every measurement taken.

3.2 User activated calibrations

- Calibration for "Ready"
- System calibration
- Conductivity calibration
- 1P calibration
- 2P calibration incl. O₂
- 2P-O₂ calibration
- 2P calibration without O₂

Press:

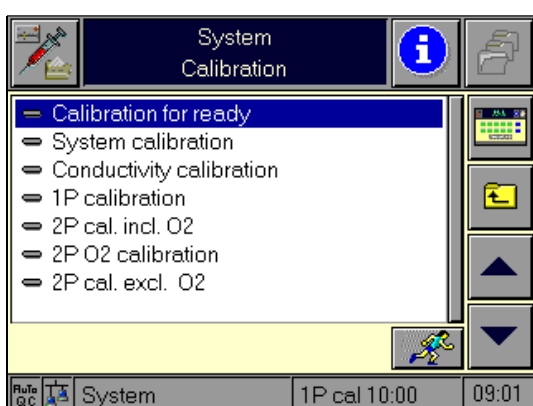
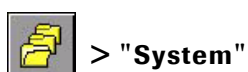


Fig. 1

Using the "up / down" buttons you may now select the desired calibration.

Start the selected calibration by pressing the  button.

3.2.1 Calibration for "Ready"

The Roche OMNI C automatically selects the calibration that is required to transfer all parameters to the "Ready" status.

3.2.2 System calibration

See page 3-1!

3.2.3 Conductivity calibration

Calibrate the conductivity system with the C1 and C2 calibration solutions in order to determine the actual mixing ratio in combination with the mixing system.

3.2.4 1P calibration

This calibration is a 1 point calibration (incl. O₂) of all parameters.

3.2.5 2P calibration incl. O₂

This calibration is a 2 point calibration of all parameters.

3.2.6 2P O₂ calibration

This calibration is a 2 point calibration for the PO₂ electrode.

3.2.7 2P calibration without O₂

This calibration is a 2 point calibration of all parameters except PO₂.

4 Measurement

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4 Measurement

4.1 Preanalytics

4.1.1 Sample collection



Follow the usual applicable safety precautions when drawing blood samples. When handling blood samples, there always exists the danger of transmission of HIV, hepatitis B and C viruses or other pathogens transmissible by blood. Employ suitable blood sampling techniques in order to reduce risk to personnel. Always wear protective gloves and suitable protective clothing.

Please refer to NCCLS document M29-T2, "Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue – Second Edition" for guidelines and additional information about handling blood samples.

Sample acquisition

Only qualified personnel may perform the collection of blood needed for analytical purposes.



The puncture site may never be squeezed! Mixing the blood sample with tissue fluid may lead to the premature onset of clotting despite sufficient heparinization of the sample collection containers! Incorrect sample collection or the use of an unsuitable sample collection container may lead to errors and discrepancies in the measurement values.

See, for example, NCCLS document H11-A2, "Percutaneous Collection of Arterial Blood for Laboratory Analysis – Second Edition", Approved Standard, May 1992, for detailed information about blood sampling, storage, and handling.

Acceptable anticoagulants

The only clot inhibitors that may be used for analyses in the Roche OMNI C are heparin salts. Other clot inhibitors, such as EDTA, citrate, oxalate, fluoride, and ammonium-based materials have significant influence on the blood's pH and other parameters and may not be used for this reason.

Sample collection especially for tHb, SO₂ and Hct measurement

Whole blood, especially for the analysis of tHb, SO₂ and Hct, must be thoroughly mixed immediately before analysis in order to achieve consistent distribution of red blood cells and plasma before insertion of the sample.

Carefully rotate the sample about two axes using your hand or a mechanical device or insert a metal disk or ball in the syringe before collecting the sample. Shortly before using the sample, carefully shake the syringe. The up and down motion of the disk or ball inside the syringe cylinder ensures consistent mixing.

Refer to NCCLS document C25-T, vol. 12 No.11, "Fractional Oxyhemoglobin, Oxygen Content and Saturation, and Related Quantities in Blood: Terminology, Measurement, and Reporting", Tentative Guidelines, July 1992.

4.1.2 Sample collection containers

TIP: When possible, use the sample collection systems manufactured by Roche Diagnostics.

Syringes

If using another manufacturer's product with liquid heparin as a clot inhibitor, the collection container should not be larger than required for the blood volume. This will minimize the effects of the clot inhibitor on the thinning of the blood. The use of plastic syringes is common, but there are cases when the use of plastic syringes is not appropriate, for example, when PO_2 values are expected to be outside the normal range. If very high PO_2 values are expected, the sample should be analyzed as quickly as possible after the sampling.



Use only heparinized syringes. Improper use of syringes with liquid heparin will affect the parameters, especially the ISE parameters!

Capillary tubes

The capillary tubes must have a minimum volume of 100 µl.

Capillary tubes with ceramic sealing caps should not be used because the fracture that forms when opening the capillary can damage the fill port of the Roche OMNI C. Use only capillary tubes with heat-treated ends to avoid damage to the instrument. When using stirring rods like those offered by a few manufacturers, remove these rods before inserting the sample in order to avoid clogging the Roche OMNI C.

Microsampler

The microsampler, which consists of two capillary tubes (115 µl each) in a plastic container, is ideally suited to atraumatic arterial blood collection.

Each laboratory should document the permissibility of sample containers that are used. These products vary from producer to producer and sometimes from lot to lot.



The use of sample containers or clot inhibitors other than those manufactured by Roche Diagnostics may lead to adulteration of the samples and errors and differences in the measurement values.

Roche developed a specialized sample collection container for this purpose and recommends its use for this reason.

Clot catcher

The use of a clot catcher is recommended to prevent clogging of the sample path during measurement of critical blood, for example, when sampling blood of newborns, blood from ear lobes, and blood from heels.

The clot catcher prevents blood clots and tissue particles from entering the Roche OMNI C.



The clot catcher cannot be used in "Syringe mode" and not be connected in "Capillary mode."

The capillary with attached clot catcher must be held in position!

For detailed information, please contact your Roche representative.

4.1.3 Sample handling

Whole blood

Withdraw whole blood samples using heparinized syringes, capillaries, or the microsampler. Analyze the samples as soon as possible after sampling. Remove air bubbles from the sample collection container immediately after the sampling procedure.

Immediately after withdrawing the sample with syringes, thoroughly mix the sample with anticoagulant. This can be done by rolling the sample between both hands or shaking. Properly label the samples, following the standard documentation procedure.

- Samples that are measured within 15 minutes may be retained at room temperature.
- If unable to measure samples within 15 minutes, place them temporarily in ice water. Complete the measurement within 30 minutes (but not after more than 60 minutes).
- Samples with a PO_2 level above 200 mmHg (26 kPa) should be collected in a glass container if the measurement can not be performed within 15 minutes.



When using capillaries analyze samples for tHb, SO_2 and Hct measurements immediately after sampling to ensure correct and accurate measurement results.

Despite proper sampling procedures, errors can arise in the blood gas analysis:

- due to insufficient mixing of the sample following removal and before the measurement
- due to ambient air contamination caused by air bubbles that are not removed following removal of the sample
- due to changes in metabolism in the sample

Serum

After the appearance of spontaneous clotting, process the sample in a centrifuge to separate the cellular, solid components and the fibrin from the watery serum. Transfer the serum to a suitable sample container and seal.

If it is necessary to store the sample, close the sample container tightly and cool it to 4 - 8 °C. If a sample has been cooled, warm it to room temperature (15 - 33 °C) before analysis.

Plasma

Plasma samples are obtained by centrifuging heparinized whole blood, during which the cellular components of the blood are removed from plasma.

Complete the analysis as quickly as possible.

If it is necessary to store the sample, close the sample container tightly and cool it to 4 - 8 °C. If a sample has been cooled, warm it to room temperature (15 - 33 °C) before analysis.

Plasma samples older than 1 hour must be re-centrifuged in order to remove fibrin clumps that may have formed.

4.2 Measuring procedure



If QC measurements are not performed or only incomplete or if the QC measurement result is ignored, it can lead to incorrect measurement results, which may lead to incorrect clinical decisions. Danger of personal injuries (for detailed information see chapter "Quality Control")!

In order to start a measurement, the Roche OMNI C must be "Ready" and in the "Analyzer"¹ operating mode.

Depending on the settings the entry of a password or a mandatory input (input value) may be required (see Reference Manual, chapter 3 "Operating modes" – "Setup").

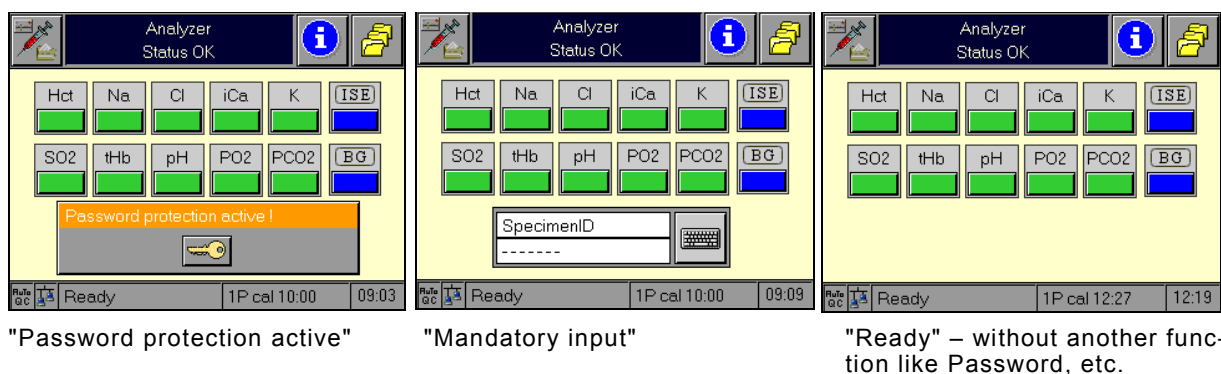


Fig. 1

You have the option of measuring samples from syringes (without needles), ampoules and capillaries.

1. For more detailed information about the operating mode "Analyzer", please see the respective chapter of these Instructions for Use and the Reference Manual!

4.2.1 Syringe mode



Improper heparinization of syringes with liquid heparin may cause false results. ISE parameters are particularly susceptible. Please contact Roche customer support regarding this matter.

- Open the flap to the designated syringe position (half-opened position). The aspiration process is started.



Fig. 2

- Attach the syringe (always remove the cannula first). Be sure that the needle sufficiently penetrates the interior of the syringe (or ampoule) in order to remove the sample without air bubbles.



Be sure that the needle does not make contact with the fill port while inserting the needle into the interior of the syringe.

If the opening of the needle is covered by the fill port, the aspiration is blocked and the sample is rejected!

If using an ampoule instead of a syringe (during a QC measurement), be sure that the ampoule does not make contact with the fill port when inserting the needle into the ampoule. The sharp edge can cause damage to the fill port.

The clot catcher cannot be used in "Syringe mode!"

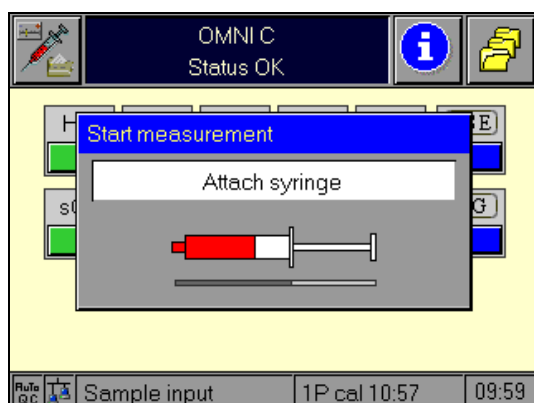


Fig. 3

- The sample is automatically aspirated (it is unnecessary to press any buttons).

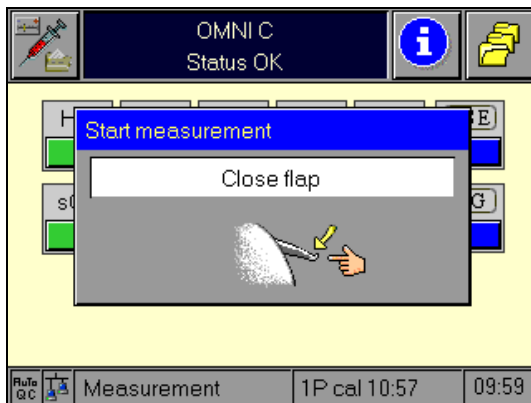


Fig. 4

- Upon display of the instruction "Close flap", remove the syringe and close the flap.
- The measurement starts.

TIP: *Never open the flap during measurement. Doing this will result in rejection of the sample!*

4.2.2 Capillary mode

- Open the flap to the labelled capillary position (completely open position). The aspiration process is started.



Open the flap slowly to avoid splattering small drops of liquid that are on the needle tip.



Fig. 5

- Insert the capillaries or the microsampler into the fill port.



The end of the capillary must be open, otherwise the aspiration process is blocked and the sample is rejected.

The clot catcher cannot be connected in "Capillary mode". The capillary with attached clot catcher must be held in position!



*Never inject the sample into the instrument!
Danger of infection!*

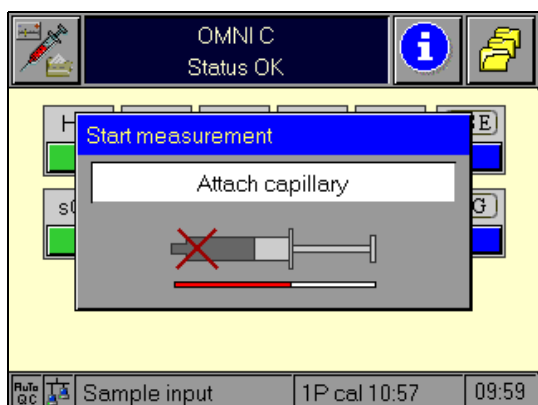


Fig. 6

- The sample is aspirated automatically into the analyzer.

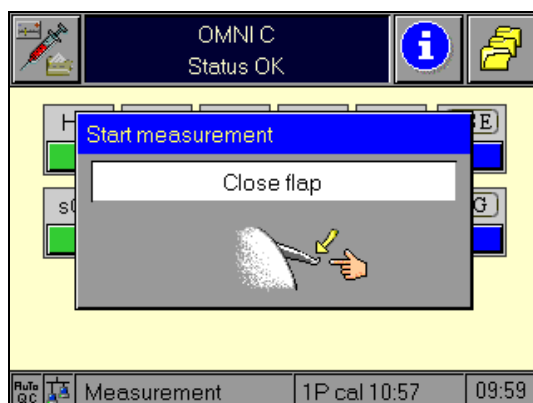


Fig. 7

- Upon display of the instruction "Close flap", remove the capillary and close the flap.
- The measurement starts.

TIP: *Never open the flap during measurement. Doing this will result in rejection of the sample!*

4.2.3 Data input

During measurement, various patient, operator, and sample-specific data may be entered. You may use a standardized or a user-specific form when entering data.

TIP: *Scanning of patient and operator data is possible!*

You can create a user-specific form that contains the desired parameters by selecting



and **Displays & reports - Measuring data - Input values**

(see Reference Manual, chapter 3, "Operating Modes" – "Setup"). Press the "More functions" button to select the predefined form. This form remains the standard until a new form is selected.

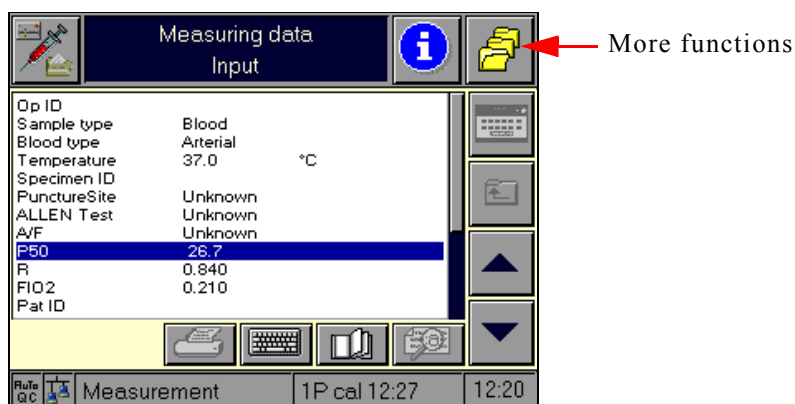


Fig. 8

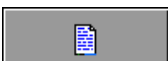
Use the "line up / line down" buttons to select the entry that you would like to modify or use your finger to select the appropriate line directly. By pressing these buttons, you can complete the following steps:

-  Input data
-  Edit the underlying entry
-  Go to additional views
-  Start a printout

4.2.4 Results display / measurement report

After the measurement is complete and all parameters have been entered, the Roche OMNI C displays the results on a standardized or user-specific form on the screen before printing the results.

Use the menu selection "Setup - Displays & reports - Measuring data - Result screen" to create a user-specific results display (see Reference Manual, chapter "Operating modes - Setup").

Press the  and  buttons to select a predefined form.

This remains the standard until a new form is selected.

You can create a user-specific measurement report by selecting



and **Display & reports > Measuring data > Measurement report**

(see Reference Manual, chapter "Operating Modes - Setup").

Press the  and  buttons to select a predefined report.

This remains the standard until a new report is selected.

Measuring data Output			
Date	18.04.2001		
Time	12:17		
Sample	15		
Baro	746.0	mmHg	
Na	139.0	mmol/L	135.0 - 148.0
Cl	100.0	mmol/L	98.0 - 107.0
pH	7.406		7.350 - 7.450
Ca	1.270	mmol/L	1.120 - 1.320
K	4.50	mmol/L	3.50 - 4.50
PO2	106.0 (+)	mmHg	80.0 - 100.0
PCO2	42.4	mmHg	35.0 - 45.0
tHb	13.9	g/dL	11.5 - 17.4

Fig. 9



Subsequent correction of the input parameters is possible by pushing this button, even after ending the measurement, as long as the measurement results are still visible on the screen.

The results are entered automatically into the database.

Change to the "Database" operating mode in order to view the database entry.

You can complete or edit additional entries in the database.

For more information, refer to chapter 8, "**Operating modes**", section "**Database**" in these Instructions for Use and to the respectively titled chapters in the Reference Manual!

5 Quality control

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5 Quality control



If QC measurements are not performed or only incomplete or the QC measurement is ignored, it can lead to incorrect measurement results, which may lead to incorrect clinical decisions.

Danger of personal injuries!

5.1 General QC concept

Roche Diagnostics always strives to ensure the highest quality standards for its products. This quality awareness is the result of a sense of responsibility toward the customer and the well-being of the patient.

The quality control is an important element of this claim. Aqueous blood gas/electrolyte QC materials, such as COMBITROL, AUTO-TROL, etc., are offered to ensure that the Roche OMNI C provides measurements of high quality to protect customers or its patients.

In order to ensure the quality of the measurement results, complete a quality control test on 3 levels (low, normal, high) after each electrode exchange and after startup of the instrument at least once daily or more often in accordance with local regulations. A quality control program for blood gas, electrolytes and tHb/SO₂ includes the analysis of sample materials with known ranges of expected values and the comparison of these values with analyzer results.

The following control material is recommended:

- COMBITROL TS
- AUTO-TROL TS

The target areas listed in the package text should be taken as 2σ areas (σ = standard deviation) (e.g. for PO₂, 2σ = 12 mmHg, 1σ = 6 mmHg).

The QC measurement results within the target value range $\pm 2\sigma$ are perfect.

If QC measurement results fall outside the target value range $\pm 3\sigma$, the parameter must be blocked!

QC measurement results that are greater than the target value $\pm 2\sigma$, but smaller than the target value $\pm 3\sigma$, lead to a QC warning and must be dealt with separately.

5.2 Important information concerning the analysis of QC measurement results



It must be ensured or checked (specifically for software versions earlier than 1.31!), whether "Multirules" rule 1 and 2 are activated (see the section "Multirules" on page 5-11) and whether the QC consequence "QC error" was assigned to the parameters (see the section "QC consequences" on page 5-13)!

With software version 1.31 and later, a blocking is automatically generated (if necessary) as long as the standard settings have not been changed!

The evaluation depends upon which σ areas are featured in the QC measurement results:

Measured value is within the target value range $\pm 2\sigma$

No consequences! The parameter is OK.

The QC measurement result is perfect, and the parameter is/remains activated for measurements.

Measured value is outside the target value range $\pm 3\sigma$

Consequence: The parameter receives the QC consequence "QC error".

The QC measurement result is not acceptable. The parameter is locked for additional measurements and may only be released for additional patient measurements after the problem has been corrected (see "QC unlock" on page 5-14).

Measured value is larger than target value $\pm 2\sigma$, but smaller than target value $\pm 3\sigma$

Consequence: The parameter receives the QC consequence "QC warning".

The user must now analyze the QC measurement results in accordance with applicable regulations or repeat the measurement.

Call up the QC statistics in the QC database (see the section "Database > QC data" in chapter 8, "Operating modes") to aid in the analysis.

The analysis can be automated by activating additional multirules (see the section "Multirules" on page 5-11).

If the result of the repeated measurement is larger than target value $\pm 2\sigma$, but smaller than target value $\pm 3\sigma$, the parameter must not be used for additional patient measurements.



If the error persists, replace the electrode and/or contact customer support!!

5.3 Material setup

TIP: Take the batch number, expiration date, sample type, and target values (ranges) as well as the corresponding barcodes from the text included in the recommended QC material.

The QC material must be defined prior to the QC measurement.

The barcode scanner facilitates easy entry of the required information.

Press the following buttons:

 **> QC materials > Set ranges**

Up to 4 different QC materials with 4 levels each can be entered.



Fig. 1

Use the "line down" button to select the material to be changed or to select a new "QC material".

Using the barcode scanner to enter data

Use the barcode scanner to enter the material code found on the packaging insert.

The material code contains the information for the material, the proper level, batch number, expiration date, and sample type.

Scan in two barcodes (the BG and tHb/SO₂ code and the ISE code) for the set ranges. The Roche OMNI C automatically assigns these.

Manual entry

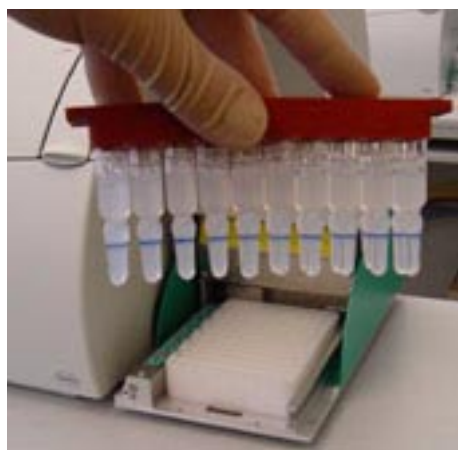
Use the  button to manually enter batch number, expiration date, sample type and target values.

Complete and save the entry by pressing twice .

5.4 Inserting AutoQC mats

Insert the mats as follows in the ampoule block:

- Open the cover of the AutoQC module.
- Take a full mat (20 ampoules) from the package.
- To mix the QC material, turn the mat twice so that the ampoules point up. Next, insert the mats in the ampoule block with the ampoule necks pointing down (see Fig. 2/1).



(1)



(2)

Fig. 2

- Place the mat in the defined position (A-F) of the ampoule block (the ampoules must no longer be visible, see Fig. 2/2).
- Repeat the same process for all additional mats.
- Close the cover of the AutoQC module.

5.4.1 Material assignment - AutoQC materials

Before beginning an AutoQC measurement, the selected AutoQC material must be assigned.

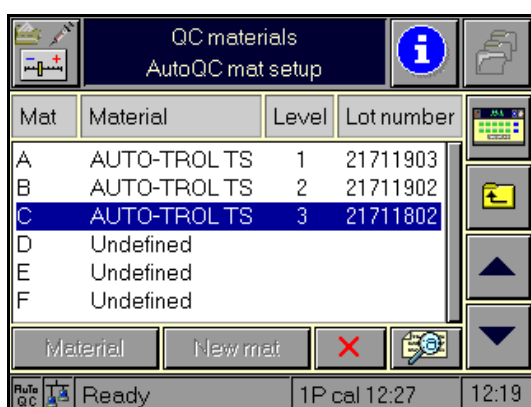


Fig. 3

Use   to select the mat to be defined (A-F).

The selected material/level combination is assigned to this mat location by pressing "Material."

"New mat": an existing and defined mat is replaced by a new one from the same batch (e.g. in case of insufficient or empty ampoules). The number of ampoules is reset to 20.



The selected material can be deleted from the mat position.

TIP: The preprogrammed times (see the section "Setting QC times") must be deleted before the material is deleted.

AutoQC mat detail screen

Press the  button to display the following:

QC materials AutoQC mat setup			
Mat	A		
Material Level	AUTO-TROL TS 1		
Lot number	21711903		
Ampoules	19 from 20		
Ready	1P cal.(A) 10:47	10:22	

Fig. 4

This screen shows detailed information about the AutoQC material placed on this mat.

Press the  button again to change to the mat assignment screen.

QC materials AutoQC mat setup			
Mat/Mat./Lev.	A/AUTO-TROL TS/1		
                   			
Ampoules	19 from 20		
Ready	1P cal.(A) 10:47	10:22	

Fig. 5

This screen shows the assignment of the selected mat.



corresponds to a full ampoule



corresponds to an empty ampoule

The assignment of the mat can be freely defined by selecting or deselecting individual ampoules.

TIP: The AutoQC cover must be open for this purpose.

5.4.2 Setting QC times

Depending on the selected material, this function is used to select the start time(s) for the AutoQC measurement(s) and/or the time for performing a manual QC measurement. After reaching the set time, a note appears in the message window.

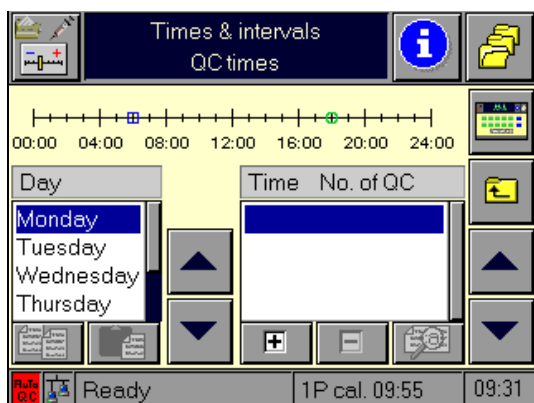


Fig. 6

Up to 16 time entries per weekday can be made for the time setting, such as when an AutoQC measurement should be started. Up to 6 materials (= 6 mats for the AutoQC) can be specified for each time.

A little marker (small magenta-colored triangles) on the time scale indicates the defined start time(s).

Setting start time(s)



Select the day from the "Day of Week" list on which the QC measurement should be performed.



Add a new time entry (you can remove it again with ).

The following screen appears (for example):

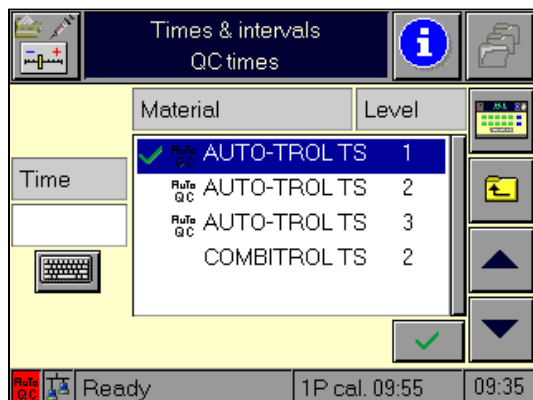


Fig. 7

Select the material/level combination from the list (this list contains all material/level combinations that were created under "Settings - QC Material - AutoQC Material" or "Settings - QC Material - Set ranges").

Confirm the selection with .



Enter the start time.

Any number of materials and times can be selected.

Press .



the attributes of the time entries can be edited.

Copying a time entry

Select a day of the week and a time entry and press  – the selected time entry of this weekday will be copied.

Select another day of the week and press  – the copied time entry will be entered for the new weekday.

These entries can be transferred to as many other weekdays as required.

**"More functions"****Measurement retries**

The number of repeated measurements (none=0, 1, 2) that are allowed in the case of an incorrect measurement can be adjusted here.

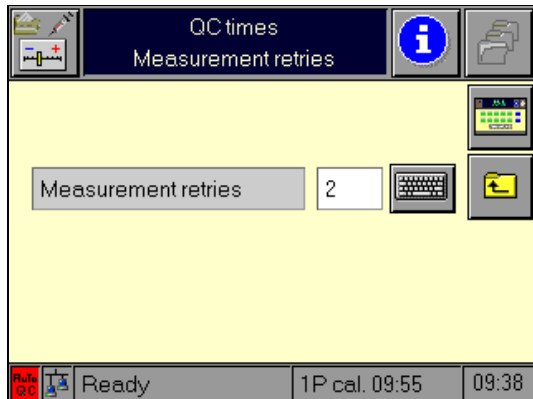


Fig. 8

5.5 QC measurement

Complete a quality control test on 3 levels (low, normal, high) after each electrode exchange and after startup of the instrument at least once daily or more often in accordance with local regulations.

5.5.1 Manual QC measurement

- Press the following buttons:



> QC measurement

- Activate the corresponding QC material (for example, COMBITROL TS) and the selected level (for example, level 1).
- Remove the ampoule of the corresponding level of the desired QC material from the packaging or of the AutoQC material from the mat.
- Gently tap the head of the ampoule with your fingernail to remove any liquid from the top.
- Break open the ampoule.



To avoid injury, protect your hands with gloves or tissues when breaking open the ampoule.

Use the control material within 30 seconds of opening.

Never reuse the ampoule!

- Open the flap to the designated syringe position (half-opened position).

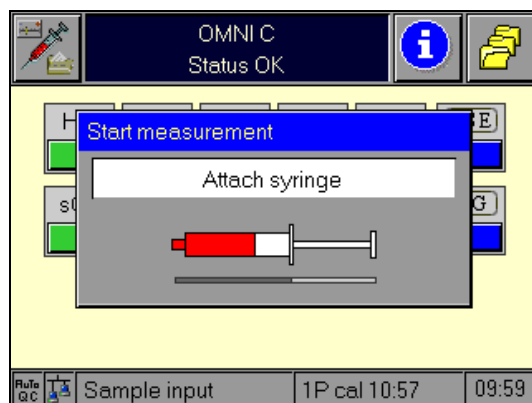


Fig. 9

TIP: *Suction the QC material directly from the ampoule!*

- Insert the needle into the ampoule.
The needle should be inserted deep enough into the fluid to avoid air bubbles.



Fig. 10



When inserting the needle into the ampoule, it is absolutely necessary to avoid contact between the ampoule and the filling port. The sharp edge can cause damage to the filling port.

- The QC sample is suctioned inward into the machine.

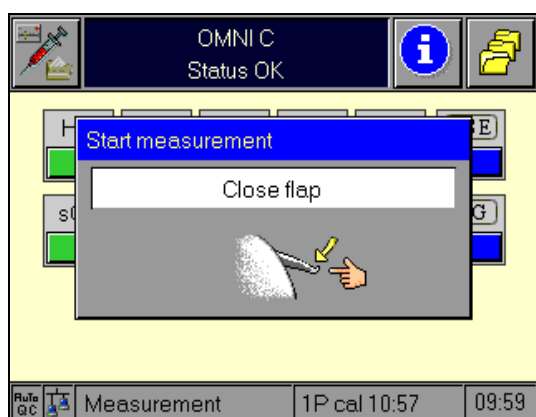


Fig. 11

- Remove the ampoule and close the flap.
- The measurement starts automatically.
- If the user does not reject the results, they are printed and automatically saved in the QC database.

Details about the operating mode "Database" can be found in chapter 8, "Operating modes", and in the reference manual, chapter 3.

5.5.2 AutoQC measurement

The AutoQC measurement can be retrieved programmatically or manually.

For this purpose, activate the corresponding AutoQC material (AUTO-TROL TS) and the selected level (e.g. level 1).

Start the AutoQC measurement by pressing  .

5.6 Multirules

The evaluation of QC results is based on the Westgard¹ rules and their interpretation for blood gas analysis². The Multirule process was derived from these rules. It permits early detection of random and systematic errors associated with the measuring device and its operation.

CAUTION: *The Multirules procedure can only be applied in connection with a suitable control material (e.g. COMBITROL TS, AUTO-TROL TS).*

The Multirule procedures produce the best results when 3 QC measurements with randomly selected levels are completed per series (time between two 2-point calibrations). A minimum of 2 QC measurements / series or 6 QC measurements / 3 series is required.

The QC concept expects Multirules rule 1 and 2 to be activated.

Press the following buttons to check the settings:



> **Parameters > Miscellaneous settings > Multirules**

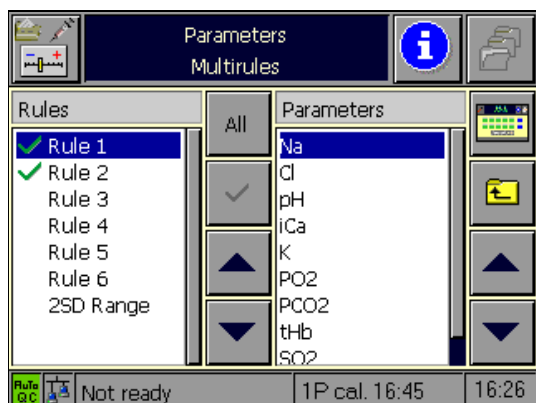


Fig. 12

Select additional desired rules in the left window and assign it to the corresponding parameter which is listed in the right window under "Parameter."

CAUTION: *It is not possible to activate all rules at the same time!*



The activation of range 2SD automatically deactivates all other rules (rules 1-6).

1. James O. Westgard, et al: *A Multi-Rule Shewhart Chart for Quality Control in Clinical Chemistry*. Clinical Chemistry, Vol. 27, No.3, 1981
2. Elsa F. Quam BS, Lorene K. Haessig BS, Marlene J. Koch BS: *A Comprehensive Statistical Quality Control Program for Blood Gas Analyzers*. Journal of Medical Technology 2:1 January 1985

5.6.1 Overview of the Multirules

Runtime between two 2-point calibrations

N_T number of individual measurements of all levels (T=total)

N_L number of individual measurements per level (L=Level)

m QC measurement value of one level and one parameter

$\bar{x}$ mean value, taken from the insert sheet or calculated based on at least 20 and no more than 100 individual measurements

σ standard deviation

Rule	Description
1. $1_{2\sigma}$	QC measurement value (m) is outside $\bar{x} \pm 2\sigma$
2. $1_{3\sigma}$	QC measurement value (m) is outside $\bar{x} \pm 3\sigma$
3. $(2 \text{ of } 3)_{2\sigma}$	Two of three QC measurement values are outside $\bar{x} \pm 2\sigma$ Observation time period: 1 series (within run) $N_T = 3$
4. $2_{2\sigma}$	2 QC measurement values (m) are outside $\bar{x} \pm 2\sigma$ Observation time period: 2 series $N_L \geq 2$
5. $6_{1\sigma}$	6 QC measurement values (m) are outside $\bar{x} \pm 1\sigma$ Observation time period: 3 series $N_T \geq 6$
6. 9_m	9 QC measurement values (m) are on the same side as the mean value. Observation time period: 5 series $N_T \geq 9$
2SD range	Defined target values (ranges)

TIP: *The Multirule process is applied after each individual measurement. Multirules are only applied to the corresponding control material (e.g. COMBITROL TS).*

5.7 QC consequences

By default, the QC consequence "QC error" should be assigned to all parameters.

Press the following buttons to set or check the assigned QC consequences:



> Parameter > Miscellaneous settings > QC Consequences

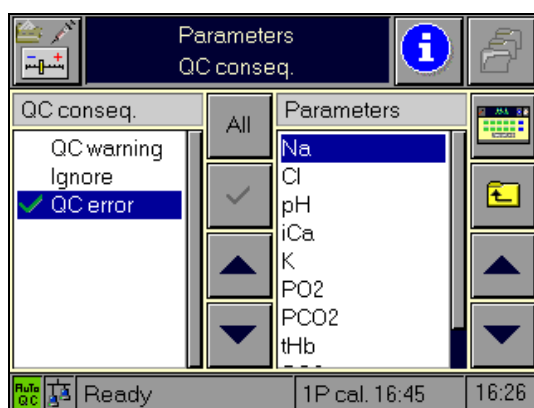


Fig. 13

Description of the QC consequences:

Ignore: if one of the set rules is broken, no consequences will be set.



QC warning: through a warning, the respective parameter will be marked in the Ready screen, but remains ready for measurement



QC error: the parameter will be blocked if one of the adjusted rules is broken. The parameter will be identified accordingly in the Ready screen.

5.8 QC unlock

5.8.1 QC warning

Proper execution of a QC measurement using the same material/level combination removes the warning.

5.8.2 QC error



A removal is only allowed if the cause of the lock is known and the error was corrected (e.g. timeout or measurement of wrong ampoule).

Automatic correction

Proper execution of a QC measurement using the same material/level combination removes the block.

Manual correction

A manual correction is only allowed if the same material/level combination is no longer available.



In this case, repeat the QC measurement with a new material/level combination of a different batch and analyze it as described under 5.2 ("Important information concerning the analysis of QC measurement results" on page 5-2)!!

A contravention violates the QC rules and must be avoided!

Press the following buttons to unlock the QC lock:



> Parameter > Miscellaneous settings > QC unlock

An overview displays all parameters that are blocked by QC measurements.

Pressing the  button removes the block for each of the blocked parameters individually.

Pressing  removes the block for all parameters.

Exchange the electrode

See chapter 6, "Maintenance", section "Exchanging the Electrodes and the MCon".

6 Maintenance

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6 Maintenance



After use, components of the Roche OMNI C, including tubing, waste container, fill port, etc., contain biological fluids and represent therefore a possible infectious risk.

Handle these components with care and according to regulations surrounding potentially infectious material. Avoid contact with skin.

Always wear gloves! Danger of infection!

6.1 Decontamination

6.1.1 Decontamination

The purpose of this procedure is to minimize the risk of infections when replacing items that were in contact with blood.

Perform these decontamination procedures regularly.

Roche recommends following a decontamination procedure in addition to regulations specific to the laboratory.



Use only liquid disinfectant such as protein remover (Roche deproteinizer) or an alcohol-based (about 70%) surface disinfectant.

Do not spray disinfectant directly onto the instrument because this could cause malfunctions in the electronics.



IMPORTANT: *Do not attempt to decontaminate any part of the instrument before shutting it down and unplugging it from the power source.*

Before plugging the instrument back in and turning it on, always wait 15 minutes to allow the disinfectant to evaporate – Danger of fire and explosion! For safety reasons, only authorized customer service personnel may decontaminate the power pack!

Regularly decontaminate the following parts of the instrument:

- Sample port module (incl. sample drip tray)
- Touch screen
- Surfaces of the instrument
- Tubing paths

Sample port module

See sections Clean needle and fill port, page 6-5 and Cleaning the sample drip tray and wash plate, page 6-14!

Touch screen

See section Cleaning the screen, page 6-20!

Surfaces of the instrument

See section Surfaces, page 6-20!

Tubing paths

Press:



> System > Wash & clean > Decontaminate all tubes

Follow the instructions on the screen.

- Open the bottle compartment cover and remove bottles C1, C2, C3.
- Fill the shutdown kit about halfway with deproteinizer.
- Insert the shutdown kit into space C3.
- Connect the tubes of the set with the connectors from C1 and C2 (Fig. 1).



Fig. 1

- Press the  button to begin decontaminating the tubes.
- Remove the shutdown kit.
TIP: Remove the remaining fluid from the tubes by briefly holding the tubes vertically, allowing the fluid to run back into the container.
- Empty the container according to local regulations and fill the shutdown kit halfway with distilled water.
- Replace the shutdown kit to the position of C3.
- Connect the tubes of the set with the connectors from C1 and C2 (Fig. 1).
- Press the  button to begin cleaning the tubes.
- Remove the shutdown kit.
TIP: Remove the remaining fluid from the tubes by briefly holding the tubes vertically, allowing the fluid to run back into the container.
- Press the  button to begin emptying the tubes.
- Re-insert the bottles C1, C2, and C3 [see section Exchanging the solutions C1 calibration solution 1, C2 calibration solution 2, and C3 fluid packs, page 6-7].
- Close the bottle compartment cover.

Recommended decontaminant**Surfaces**

70% alcohol decontaminant for bottles

Tubing paths

Protein remover (Roche deproteinizer)

- **Potential dangers**

Due to the alkaline and oxidizing character of this preparation, we cannot rule out local irritation to the skin, eyes, and mucous membranes.

- **First Aid measures**

After inhalation: breath fresh air, drink large amounts of water

After skin contact: wash with generous amounts of water, remove contaminated clothing

After eye contact: rinse eyes with generous amounts of water, contact an eye doctor

After drinking: drink large amounts of water, avoid vomiting, contact a doctor.

6.2 Daily

6.2.1 Check fill levels

Check daily the fill levels of the solutions (C1 calibration solution 1, C2 calibration solution 2) and the waste container (W waste container). Perform visual checks or select:

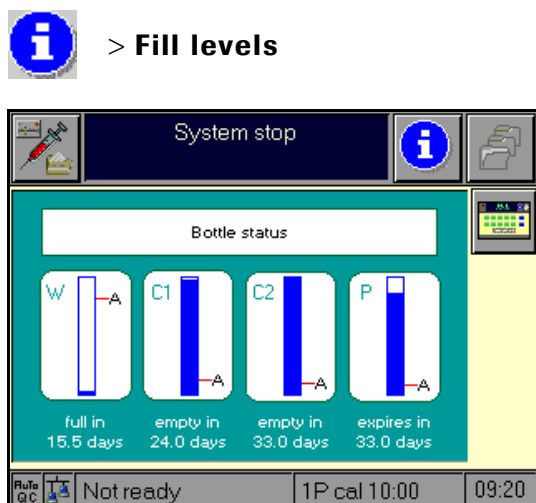


Fig. 2

Exchange empty bottles, bottles whose usage date has expired, and full waste water bottles (see section Using the empty C1 calibration solution 1 bottle as W waste container, page 6-11).

6.2.2 Check printer paper

Check daily to be sure that sufficient printer paper is available and exchange it if necessary (paper is sufficient for about 200 measurements with 15 cm / measurement) (see section Replacing printer paper, page 6-15).

TIP: *The printer paper is heat sensitive on one side only. Please make sure that you insert the paper roll correctly.*

6.3 Weekly

6.3.1 Clean needle and fill port



*Handle these parts with care – danger of injury!
Always wear gloves! Danger of infection!*

- While in the "Analyzer" operating mode, press:



> System > Wash and clean > Clean sample port module

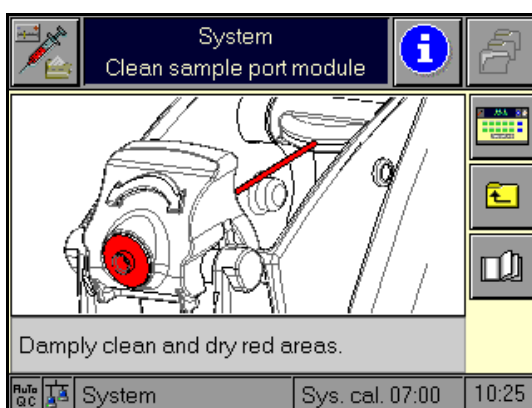


Fig. 3

- Open the flap to the labelled capillary position (completely open position).
- Use a moist (deproteinizer for example) paper towel or gauze to clean the fill port and remove any deposits on the needle (see Fig. 4/1+2).
- Close the flap to the syringe position (half-opened position).
- Clean the tip of the needle (see Fig. 4/3).



(1)



(2)



(3)

Fig. 4

- Close the flap.

6.4 Semi annual

6.4.1 Replacement of the peristaltic pump tubes

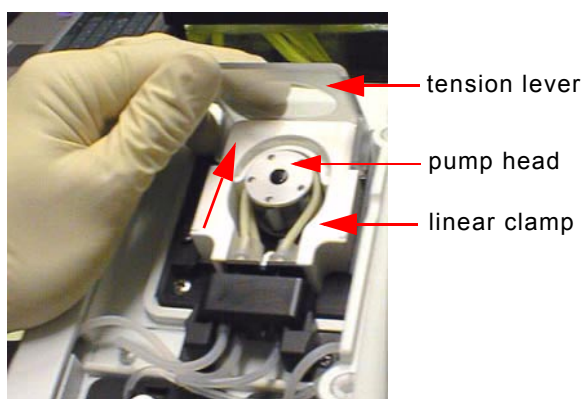
While in the "Analyzer" operating mode, press:



> System > Tools > Tubing exchange > Replace PP tubing

Follow the instructions on the screen and proceed as follows:

- Open the top cover.
- Open the peristaltic pump's clear plastic cover (tension lever). Push the linear clamp (white plastic part) upwards (see Fig. 5/1).
- Remove the complete tubing set (tubing holder and tubing) (see Fig. 5/2).



(1)



(2)

Fig. 5

- Check if the five rollers on the peristaltic pump rotate easily. If defective, please contact customer service!
- Place the new tube around the rolling wheel.
- Close the acrylic glass cover (tension lever). This presses the tubing holder into the sealer.
- Close the top cover.



The tubes may drip after disconnection. Remove excess fluids with a clean, absorbent cloth.

6.5 Sample-dependent maintenance procedures

6.5.1 Exchanging the solutions C1 calibration solution 1, C2 calibration solution 2, and C3 fluid packs

C1 calibration solution 1 and C2 calibration solution 2

Depending on the rate of measurement and/or the on-board stability, these solutions should be exchanged every 2-4 weeks. The screen displays the appropriate information.



The bottles of C1 and C2 solution must always be exchanged simultaneously. Fluids remaining in the bottles may never be mixed together because this may result in calibration errors!

Reuse of this bottle can lead to errors during calibration! Insert another bottle that has not yet expired.

C3 fluid pack

Depending on the rate of measurement and/or the on-board stability, this fluid pack should be exchanged every 4-6 weeks. The screen displays the appropriate information.



Reuse of this bottle can lead to errors during calibration! Insert another bottle that has not yet expired.

It contains the following solutions:

- Solution for calibrating the PO_2 zero point
- Solution for conditioning the Na^+ electrode
- Cleaning solution
- Reference solution

Implementation:

- Open the bottle compartment cover. The following screen appears:

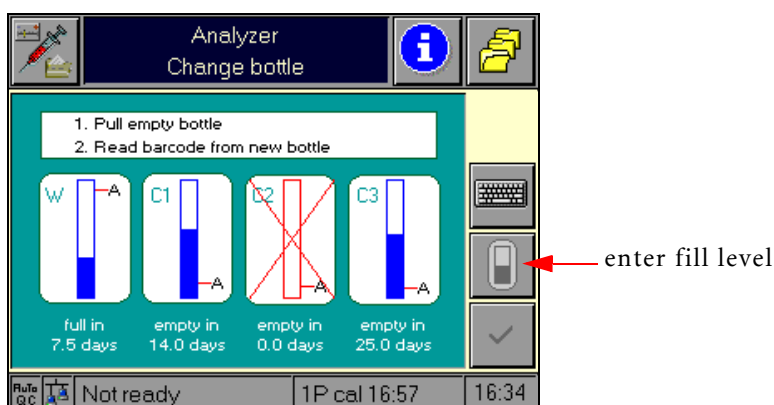


Fig. 6

- Open the docking mechanism and remove the bottles that are to be exchanged (see Fig. 7).



Fig. 7



Dispose of the bottles according to local regulations (hazardous waste!)

- Next, scan in the barcode of new bottle.
 - If a barcode scanner is not available, enter the correct barcode with the numerical keyboard and confirm your entry.
 - The Roche OMNI C recognizes the correct solution and checks the expiration date. The respective bottle blinks on the screen.
- If the bottle has passed the expiration date, the screen displays a warning.



Reuse of this bottle can lead to errors during calibration! Insert another bottle that has not yet expired.



Remove rubber sealings from C3 Fluid Pack before inserting it!

- Push the bottle onto the proper position until it engages.
- Close the docking mechanism.

After inserting a full bottle, confirm with .

If inserting a bottle that has already been partially used, press the  button and enter the fill level.

TIP: *Use the markings on the label to estimate the fill level of a bottle that is partially full.*

- A numerical keyboard appears on the display. Enter the correct fill level in % and confirm with the OK button.
- Close the bottle compartment cover. The solutions are automatically aspirated upwards (detection in the flap).

6.5.2 Waste material

Remove the waste container (W waste container)

- Open the bottle compartment cover. The bottle exchange image appears on the display (see Fig. 8).

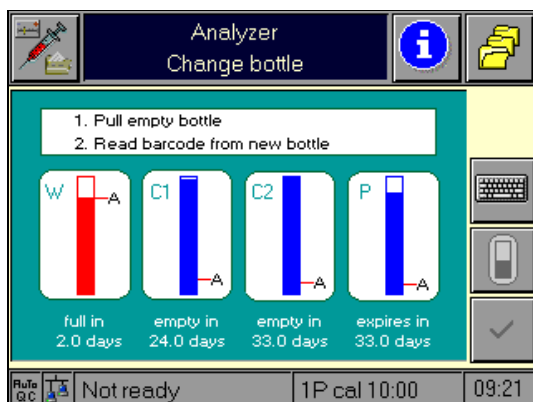


Fig. 8



Always wear gloves! Danger of infection!

- Open the docking mechanism and remove the waste container.



Dispose of the waste container according to local regulations (hazardous waste!).

Empty the waste container



Always wear gloves! Danger of infection!

- Place the bottle tool on the screw cap (Fig. 9).

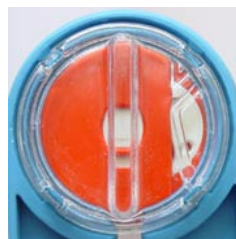


Fig. 9

- Open the screw cap by pressing the grips together and rotating them counter clockwise (Fig. 10).



Fig. 10

- When removing the screw cap, make sure that the green element inside the bottle is not moved or removed (Fig. 11).



Fig. 11



Empty the waste material and decontaminate the container according to local regulations (hazardous waste material!).

- Screw the cap back onto the bottle. The cap must be screwed shut until completely closed!

Using the empty C1 calibration solution 1 bottle as W waste container

- Remove the sticker from the empty bottle of C1 solution (see Fig. 12).

TIP: This sticker may not be reused – discard immediately.

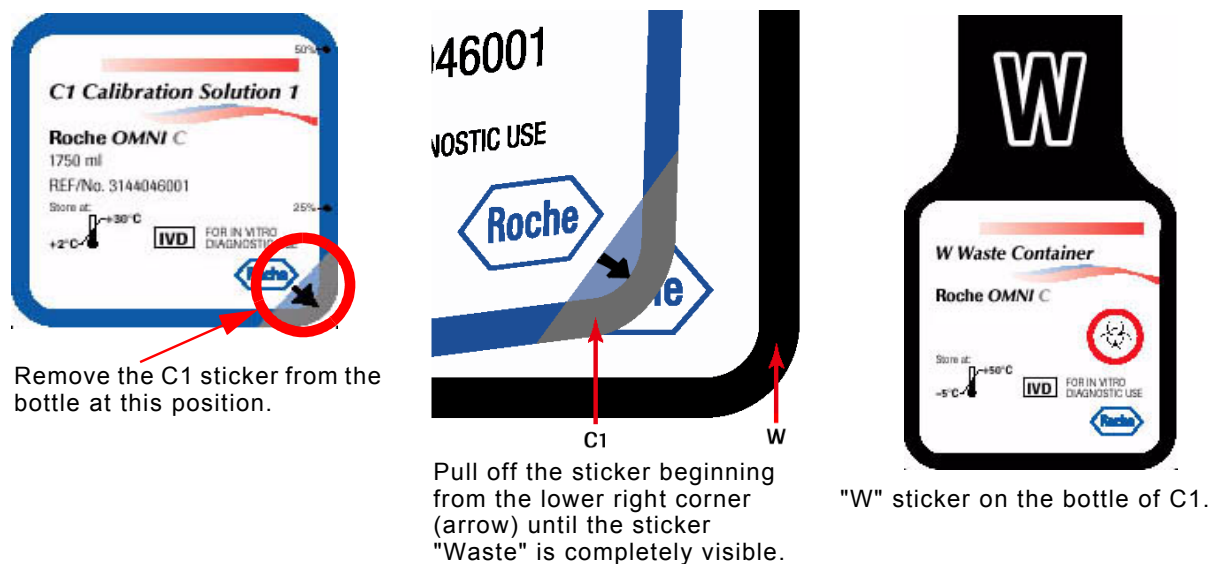


Fig. 12

Installing the waste container

- Push the bottle to the position for "W" until it engages.
- Close the docking mechanism and confirm.
- The fill level monitoring feature recognizes the waste container as "empty".
- When inserting a bottle that is not completely empty, press the  button. A numerical keyboard appears on the display. Enter the approximate fill level in % and confirm with the OK button.
- Close the bottle compartment cover.



CAUTION! If the W waste container is mistakenly reused as C1 calibration solution 1, a section of the tubing must be exchanged!

Please contact customer service immediately!

6.5.3 Exchanging the fill port holder

The fill port holder is part of the sample port module and should be exchanged every 1 to 6 months depending on the rate of measurement.



*Handle these parts with care. Danger of injury!
Always wear gloves! Danger of infection!*

- While in the "Analyzer" operating mode, press:



> System – Wash and clean – Clean sample port module

- Open the flap to the labelled capillary position (completely open position).
- Rotate the fill port holder in the direction of the arrow (see the marking on the fill port holder). It will come out of the axis and snap out of place (see Fig. 13/1)
CAUTION: Do not bend the needle!
- Carefully remove the fill port holder from the needle (see Fig. 13/2).



Axis

(1)



(2)

Fig. 13

- Place the new fill port holder (with integrated fill port) over the needle. It is easier if you turn the holder around so that the bottom side is showing on top (see Fig. 14).

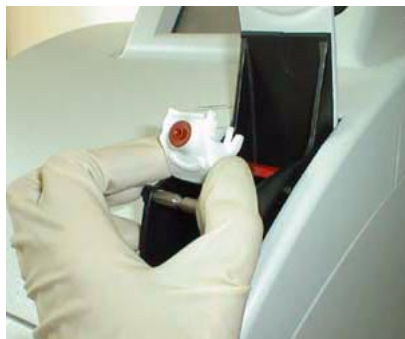


Fig. 14

- Snap the fill port holder evenly onto the axis (do not bend the needle!).



Fig. 15

- Close the flap.



Dispose of the used fill port holder in accordance with local regulations (hazardous waste!).

6.6 Unscheduled

6.6.1 Cleaning the bottle compartment

- Open the bottle compartment cover. The bottle exchange image appears on the display (see Fig. 8).
- Open the docking mechanisms and remove all bottles.
- Clean the bottle compartment with a towel soaked in disinfectant (deproteinizer for example).
- Re-insert the bottles (see section Using the empty C1 calibration solution 1 bottle as W waste container, page 6-11 and Installing the waste water container, page 6-11).

TIP: Do not scan a barcode!

- While in the "Analyzer" operating mode, press:



> **System > Tools > Fluid actions > Auto preparation routines**

- Select successively "Prepare Calibration Solution C1" and "Prepare Calibration Solution C2".

Start the process with



6.6.2 Cleaning the sample drip tray and wash plate

The sample drip tray and the wash plate are parts of the sample port module.



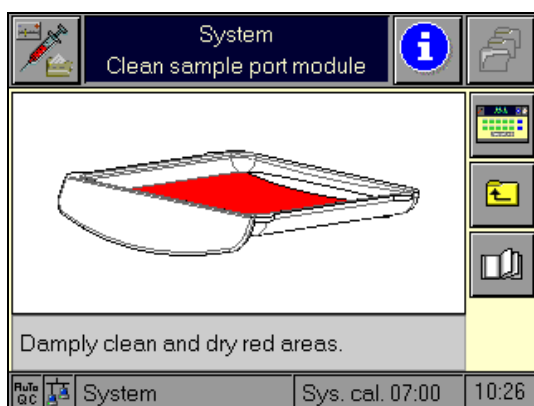
Handle these parts with care. Danger of injury!

Always wear gloves! Danger of infection!

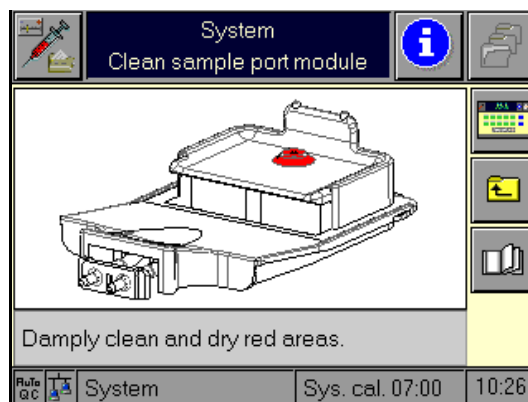
While in the "Analyzer" operating mode, press:



> **System > Wash and clean > Clean sample port module**



Sample drip tray



Wash plate

Fig. 16

- Open the flap to the labelled capillary position (completely open position).
- Remove the sample drop cup and clean it according to local regulations (see Fig. 17/1).
- Open the bottle compartment cover.
- Remove the red tube connector from the wash plate (see Fig. 17/2)
- Push the wash plate down (to unlock) and pull it out (see Fig. 17/3). The wash plate is locked when the plug is sticking out and cannot be removed.

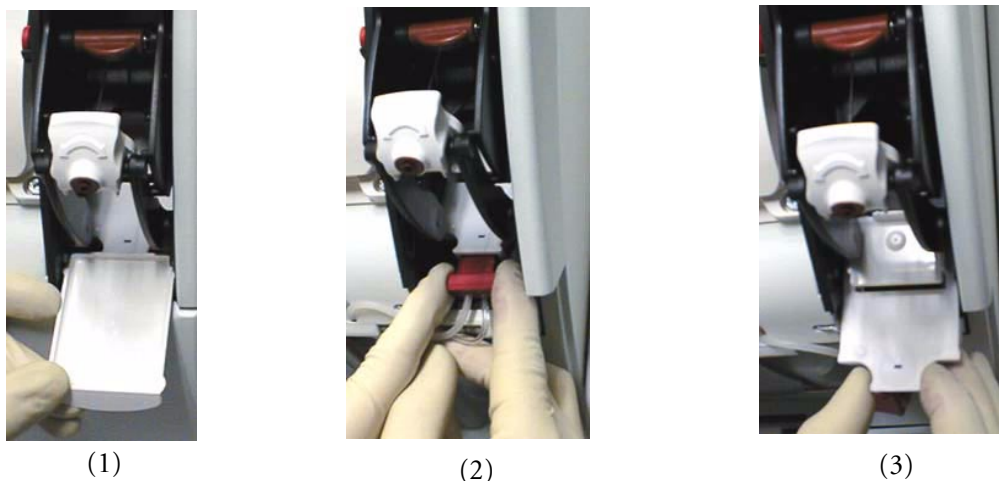


Fig. 17

- It is best to clean the wash plate under running water. Then, dry well.
- Then push the wash plate back in completely and attach the tube plug.
- Push the sample drip tray in.
- Close the flap.
- Close the bottle compartment cover.

6.6.3 Replacing printer paper

TIP: The printer paper is heat sensitive on one side only. Please make sure that you insert the paper roll correctly.

- Open the printer cover.
- Remove the empty cardboard roll.
- Cut off, at a right angle, the start of the paper.
- Place the new paper roll into the holder.
- Make sure that the printer lever is in the "down" position (see Fig. 18).
- Feed in the beginning of the paper according to the sticker on the inside of the printer cover (see Fig. 18).

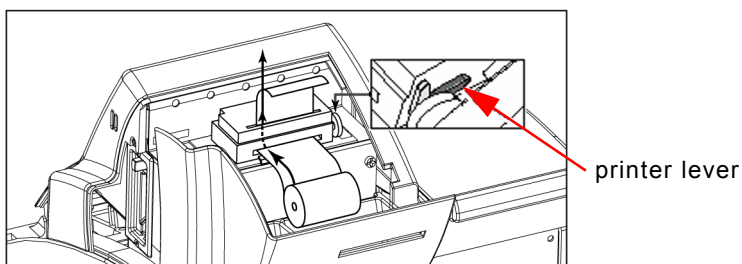


Fig. 18

- The paper is automatically pulled into the printer.

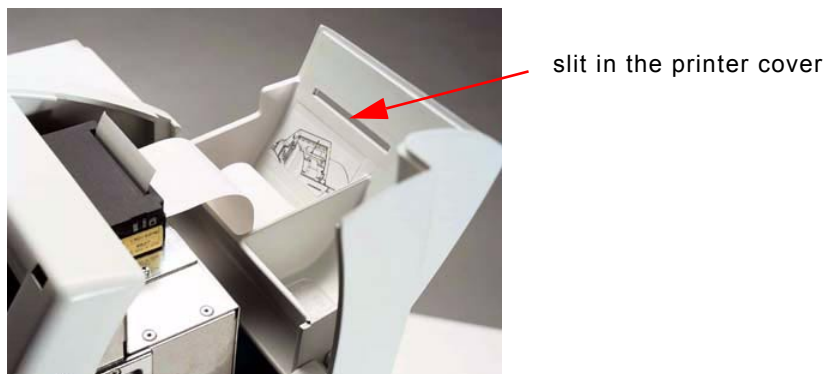


Fig. 19

- Close the printer cover and feed the paper outward through the slit in the printer cover.

6.6.4 Replacement of the electrodes and the MCon

- Open the top cover and measurement chamber cover.
The following image appears on the screen:

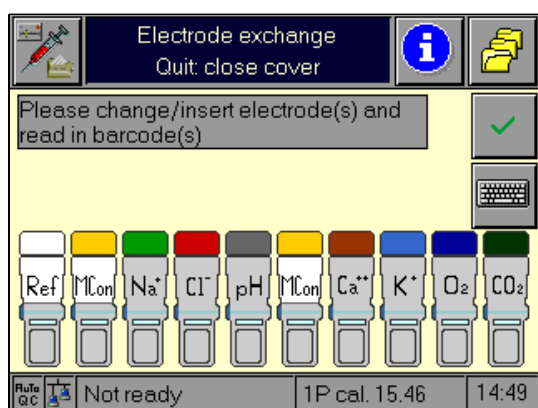


Fig. 20

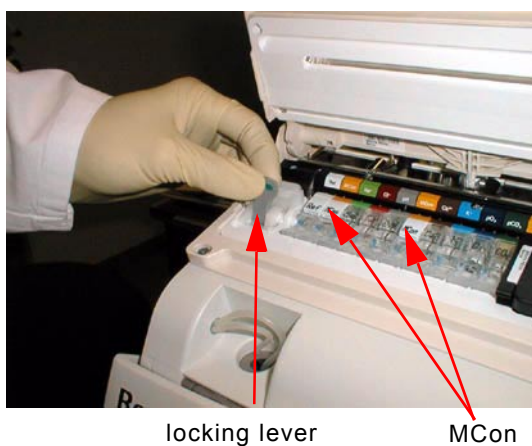


Fig. 21

- Open locking lever.
- Take the appropriate electrode/MCon and move it to the left.
- Remove the particular electrode/MCon.



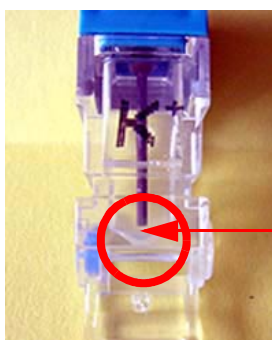
Dispose the electrode(s)/MCon according to local regulations (hazardous waste!).

- If necessary, clean the measuring chamber with a towel soaked in disinfectant (deproteinizer for example).

TIP: *If a new electrode is not available, insert a dummy electrode instead.*

MCon and the reference electrode may not be replaced with a dummy electrode.

- Prevent the formation of gas bubbles in the inner electrolyte of the electrodes (see Fig. 22/1).
- If necessary, remove air bubbles by holding the electrode vertically and by tapping lightly with your fingernail against the electrode body (see Fig. 22/2).



(1)



(2)

Fig. 22

- Insert the new electrode/MCon according to the colour code.
- Push all electrodes slightly to the right so that they are lined up together without gaps.
- Close the locking lever.
- Inspect the electrical contact of the electrodes by checking if they fit tightly.
- Scan the barcodes located on the inner packaging of each electrode or enter the barcodes manually with the help of  .



Fig. 23

- The corresponding electrode begins blinking on the screen.
Confirm with the  button.
- Carefully close the measuring chamber and then the top cover.
- A system calibration automatically starts.
- After completing the calibration, perform a quality control measurement on all three levels. While doing so, note the conformance of the results with the target values (see chapter 5, Quality control).

6.6.5 Replacement of the reference electrode

- Open the top cover and measurement chamber cover.
The following image appears on the display:

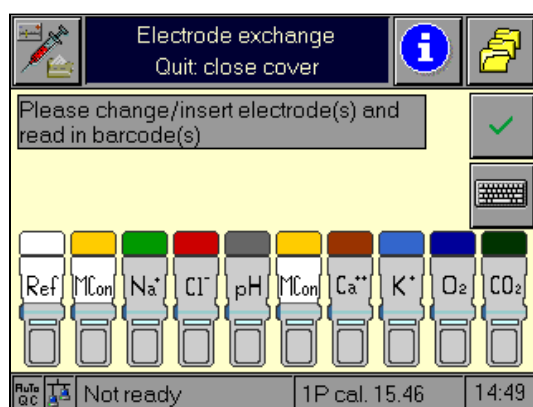
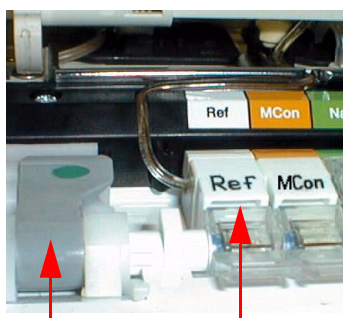


Fig. 24

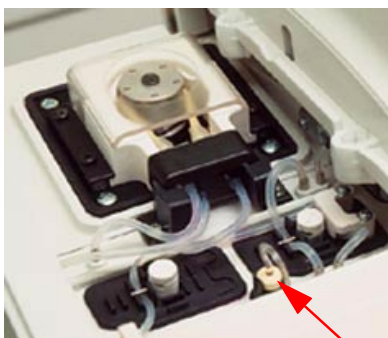
- Open locking lever.
- Remove the reference electrode.



locking lever reference electrode

Fig. 25

- Pull off the white plug (see Fig. 26/2).



(1)



(2)

Fig. 26

- Insert the new reference electrode.
- Place the tube back into the tube guide slot.

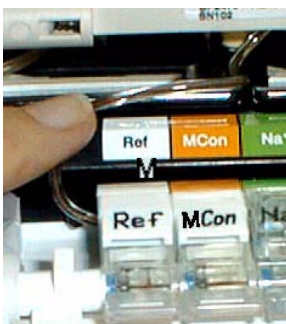


Fig. 27



If the tube does not lie precisely inside the guides, it may become pinched and thereby prevent aspiration of the reference solution, resulting in calibration and measurement errors.

- Affix the white plug at the end of the reference electrode tube (see Fig. 26).
IMPORTANT: push the plug in completely.
- Close the locking lever.
- Inspect the electrical contact of the electrodes by checking if they fit tightly.
- Scan the barcode on the packaging of the inserted electrodes or enter it manually with the help of .
- The corresponding electrode begins blinking on the screen.
Confirm with the  button.
- Close the measurement chamber and the top cover.

6.6.6 Cleaning the measurement chamber

- Open the top cover and measurement chamber covers.
 - Remove all electrodes as described in section: **Replacement of the electrodes and the MCon**, page 6-6.
 - Clean the measuring chamber with a towel soaked in disinfectant (deproteinizer for example).
 - Re-insert the electrodes.
- TIP: Do not scan a barcode!*

6.6.7 Cleaning the screen

While in the "Analyzer" operating mode, press:



> System > Wash & clean > Clean screen

The keys on the screen are deactivated for 30 seconds.



*Clean only with a moist cloth (for example, one that is soaked with disinfectant).
Do not use sprays!*

After 30 seconds, the display changes back into its active condition.

6.6.8 Surfaces



IMPORTANT: *Do not attempt to decontaminate any part of the instrument before shutting it down and unplugging it from the power source.
Before plugging the instrument back in and turning it on, always wait 15 minutes to allow the disinfectant to evaporate – Danger of fire and explosion!
For safety reasons, only authorized customer service personnel may decontaminate the power pack!*

Regularly decontaminate all outside surfaces of the instrument, including all covers (for example, printer cover, bottle compartment cover, top cover). For these tasks, use the decontaminant in accordance with local regulations.

Very dirty surfaces should first be cleaned with swabs or paper towel of gauze that have been soaked in distilled water. Spray all removable covers (top cover, bottle compartment cover) with surface disinfectant and then wipe them down with swabs or paper towel of gauze. Always respect the time necessary for proper effects.



IMPORTANT: *Never spray parts that cannot be removed or that are inside the instrument!*

6.6.9 Adjusting the screen

While in the "Analyzer" operating mode, press:

 **> Test > PC components > Touch screen**

Use this test function to test the functionality of the touch screen and to adjust the screen.

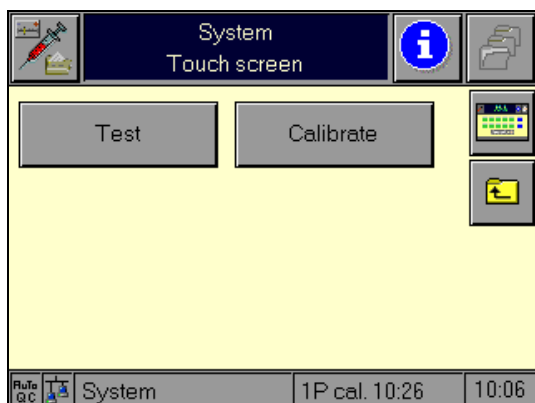


Fig. 28

By pressing the "Test" button, you can check if the entire (black) area is active as a touch-sensitive surface (see Fig. 29).

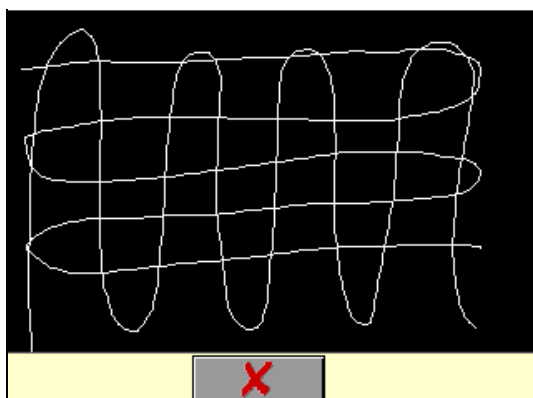


Fig. 29

By pressing the "Calibrate" button, you can use a pencil or other pointed object (but which is not too hard, to avoid scratching the surface) to touch the white points in the upper left and lower right corners. After release, the instrument will accept the exact position. From this time on, the instrument will use the touched points to calculate the offset between the displayed pixels and the touch screen. After a point has been accepted, the arrow disappears. The point itself remains visible and active (pressing the position again re-establishes the point) (see Fig. 30).

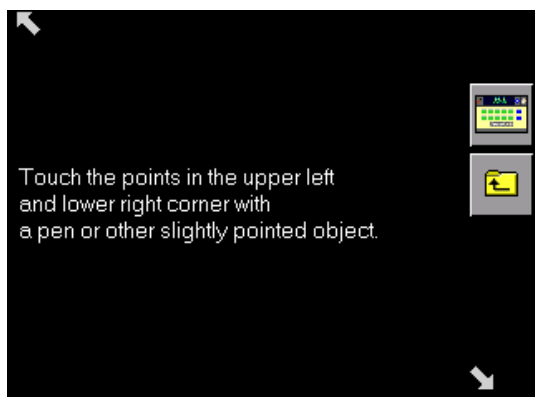


Fig. 30

After leaving the window, the new correction values take effect.

6.7 ***Additional maintenance procedures***



The listed maintenance procedures should only be performed by the customer support or by well-trained personnel. For detailed description, please refer to the Service Manual!

- Yearly service
- Check the baro value
- Fill level measurement – waste material: check / correct accuracy
- Pump head
- Replacement of the entire tubing system

6.8 Maintenance overview

While in the "Analyzer" operating mode, press:



> System > Tools > Maintenance

The overview shows a list of all maintenance entries.

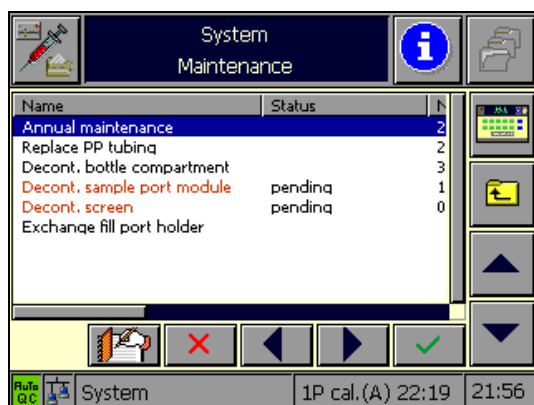


Fig. 31

The following warnings are default entries and can neither be deactivated nor modified:

- Annual service
- Replace PP tubing
- Decontaminate bottle compartment
- Decontaminate sample port module
- Decontaminate screen
- Replace fill port holder

Upcoming services are displayed in "red" in the list



marks the service as performed. The next cycle period is calculated.



marks the service as "skipped" in the instrument database.



is used to create an independent entry to be stored in the instrument database.

6.9 Maintenance scheduler

Additional services can be added to the list in the menu



> Times & intervals > Maintenance scheduler

starting with the top level of the analyzer mode

For the exact description, see the section "Settings" in chapter 3, "Operating modes," of the Reference Manual!

7 *Trouble shooting*

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7 Trouble shooting



After use, components of the Roche OMNI C, including tubing, waste container, filling port, etc., contain biological fluids and represent therefore a possible infectious risk.

Handle these components with care and avoid contact with skin.

Use gloves.

7.1 System stops



IMPORTANT: *system stops should be corrected as quickly as possible!*

For example:



Abb. 1

7.1.1 General information

During situations when a proper function of the analyzer is not possible, system stops are displayed on the screen. The purpose is to display the errors, to remove the cause of the system stops and to bring the analyzer back to "Ready".

A stop of all running actions will occur if danger for the user (e.g. by an overflow of the waste while opening the docking mechanism of the waste container) or for the analyzer exists or a proper operation of the analyzer is not possible because of technical problems.

If a proper operation is not possible, but the complete control of the functions of the analyzer is available (e.g. temperature alarm, measuring chamber cover open, flap open, fill level alarm) all running actions will be finished and Mix 1 will be aspirated into the measuring chamber; the resulting measuring data will be marked resp. discarded.

Unrecoverable system stops remain on the screen and fulfil an emergency program if possible, so that the analyzer stays operating (wetting of the electrodes / keeping the tubing free).

It is possible to access the menu "System" if no automatic actions are currently performed. When changing to the menu "System" during a "system stop", the "system stop" will not be terminated, but reactivated when the menu "System" is closed again. If e.g. there is a change from a "Temperature system stop" to the menu "System" and the menu "System" is closed again, the analyzer will display the system stop "Temperature" again. In the case a system calibration has been started in the menu "System", it can not be conducted immediately because the "system stop" has to be removed first.

After all "system stops" have been removed, "system stop consequence actions" will be executed. There is a common list of consequence actions, which impedes double actions. This means that if e.g. "washing" was activated several times, it is then performed only once.

Possible consequence actions are:

- Warm-up
- Sample sensor calibration
- Prepare solution C1
- Prepare solution C2
- Prepare Pack C3 solutions
- Fill the AutoQC wash tube
- Fill the FMS reservoir
- Wash
- Wash AutoQC
- Conductivity calibration
- System calibration
- Waste container fill level measurement
- Aspirate Mix1

7.2 *List of system stops*

7.2.1 *3001 Measuring chamber cover open*

Cause

- The measuring chamber cover is open
- The measuring chamber cover sensor (hall sensor) is defective
- The measuring chamber cover cable is defective

Remedy

- Close measuring chamber cover
- Check the measuring chamber cover sensor ("More functions > System > Test > Control sensors > Monitoring sensors")
- In case of recurrence, call customer service (check cable, change components if necessary)!

Consequence actions

1. After opening for longer than 5 seconds: Warm-up
2. Wash
3. After changing (an) electrode(s): system calibration

7.2.2 *3002 Bottle compartment cover open*

Cause

- The bottle compartment is open
- The bottle compartment cover micro switch is defective

Remedy

- Close bottle compartment cover
- Check to be sure that the bottles are inserted completely
- Check the bottle compartment cover micro switch ("More functions > System > Test > Control sensors > Monitoring sensors")
- In case of recurrence, call customer service (bottle compartment cover micro switch change if necessary)!

Consequence actions

- C1 changed: prepare solution C1, fill FMS reservoir, conductivity calibration
- C2 changed: prepare solution C2, fill FMS reservoir, conductivity calibration
- C3 changed resp. C3 docking mechanism micro switch operated: prepare C3 solutions
- Waste container changed resp. micro switch operated: Waste container fill level measurement

7.2.3 3003 Flap open

Cause

- The flap was opened:
 - during a measurement
 - during a calibration
 - during another system stop
 - in menu "System" and menu "System" is being closed
- The flap detection is defective

Remedy

- Close flap
- Check function of the flap detection board ("More functions > System > Test > Control sensors > Monitoring sensors"), change if necessary
- In case of recurrence, call customer service!

Consequence actions

- Wash

7.2.4 3004 Analyzer error

Cause

- The measurement progress was incorrect

Remedy

- Press "OK" button
- Switch the analyzer off/on
- In case of recurrence, call customer service (the electronics is defective, change components if necessary)!

Consequence actions

- Wash

7.2.5 3005 Memory error

Cause

- Fundamental software functions can not be performed (memory problems, file system problems), the correct operation of the Roche OMNI C can not be guaranteed

Remedy

- Press the "Reboot" button
- In case of recurrence, call customer service (the electronics is defective, change components if necessary)!

7.2.6 3006 Temperature error

Cause

- The module temperature is outside of the specified range:
- Measuring chamber (left and right): 37.00 °C ± 0.2 °C
- Measuring chamber cover: 37.00 °C ± 0.2 °C
- tHb-/SO₂ module: 37.00 °C ± 0.2 °C
- A heating device is defective
- The measuring chamber cover cable is defective
- A temperature sensor is defective

Remedy

- Reduce / raise the room temperature
- In case of recurrence, call customer service!

7.2.7 3009 Conductivity cal. error

Cause

- The conductivity calibration has failed

Remedy

- Press the "OK" button (start a system calibration)
- In case of recurrence, call customer service!

Consequence actions

- System calibration

7.2.8 3010 AQC cover open

Cause

- The AutoQC cover is open
- The AutoQC cover sensor (Hall sensor) is defective

Remedy

- Close the AutoQC cover
- Check the AutoQC cover sensor ("More functions > System > Test > Control sensors > Monitoring Sensors").
- In case of recurrence, call customer service (change components if necessary)!

7.2.9 3012 User system stop

Cause

- The automatic fluidic procedure completion of some system stops can be interrupted by a User system stop (by pressing the "Stop" button), e.g. in order to get immediate access to the "More functions" button.

Remedy

- Press the "OK" button (terminate the "User system stop")
- In case of recurrence, call customer service!

Consequence actions

- Aspirate Mix1

7.2.10 3013 Fluid pack switch

Cause

- The docking mechanism of Fluid Pack C3 has been opened (micro switch activated)
- The Fluid Pack C3 docking mechanism micro switch is defective

Remedy

- Close docking mechanism Fluid Pack C3
- Check micro switch ("More functions > System > Test > Control sensors > Monitoring sensors"),.
- In case of recurrence, call customer service (change if necessary)!

Consequence actions

- Auto-preparing of Fluid Pack C3 solutions

7.2.11 3014 Fill level alarm

Cause

- The solutions C1, C2 and/or C3 are empty (below alarm level) or are set to "empty"
- The Waste container W is full (above alarm level)
- The expiry date of the solutions is exceeded
- The on-board lifetime of the solutions is exceeded (C1/C2 = 28 days; C3 = 42 days)

Remedy

- Change solutions C1, C2 and Pack C3
- Change or empty the Waste container W according to the instructions
- In case of recurrence, call customer service!

Consequence actions

- C1 changed: prepare solution C1, fill FMS reservoir, conductivity calibration
- C2 changed: prepare solution C2, fill FMS reservoir, conductivity calibration
- C3 changed resp. C3 docking mechanism micro switch operated: prepare C3 solutions
- Waste container changed resp. micro switch operated: Waste container fill level measurement

7.2.12 3015 Waste container full

Cause

- Waste container is full

Remedy

- Change or empty Waste container according to the instructions

Consequence actions

- Waste container fill level measurement

7.2.13 3016 Waste container switch

Cause

- The Waste container (W) has been removed
- The Waste container micro switch is defective

Remedy

- Reinsert the Waste container
- Check Waste container micro switch ("More functions > System > Test > Control sensors > Monitoring sensors").
-
- In case of recurrence, call customer service (change if necessary)!

Consequence actions

- Waste container fill level measurement

7.2.14 3017 Pump cal. error

Cause

- The pump calibration (rotational speed adjustment of the pump) failed

Remedy

- Check under "More functions > Test > Valves & Aggregates > Peristaltic pump". if values inside the following limits are displayed:
Pump volume: 40 - 70µl
FMS volume: 920 - 1050µl
- If the displayed values are outside of the limits, perform a FMS volume determination and correct the FMS volume value.
- In case of recurrence, call customer service!

Consequence actions

- Aspirate Mix1
- Conductivity calibration

7.2.15 3018 Sample detection failed

Cause

- The sample detection with sample sensors (SS1 and SS2) failed
- The sample sensor board is defective

Remedy

- Press the "OK" button (start a Sample sensor calibration)
- In case of recurrence, call customer service!

Consequence actions

- Sample sensor calibration
- Fill FMS reservoir
- Wash

7.2.16 3019 Out of operation

Cause

- The instrument has been taken out of operation

Remedy

- Perform the installation procedure, see chapter 1 "Introduction", section "Installation".

7.2.17 3020 Economy mode

Cause

- The economy mode has been started manually or automatically

Remedy

- Manual termination by pressing the "Abort" button
- Automatic termination by pre-set stop time

7.2.18 3023 Waste Container level undefined

Cause

- The actually measured waste container fill level differs by more than 4 cm from the calculated/set value

Remedy

- The waste container fill level must be set roughly (+/- 4 cm) corresponding to the actual fill level in the waste container
- In case of recurrence, call customer service!

Consequence actions

- Wash
- Waste container fill level measurement

7.2.19 3024 Flash memory full

Cause

- The internal flash memory has less than 8 KB space left for saving additional data

Remedy

- Delete data records (database entries, protocols, log data) in order to free up additional memory (see chapter 8, "Operating modes", section "Database" or Reference Manual, chapter 3, "Operating modes", section "Setup – Displays and reports")

Important! In order to effectively free up additional memory, the functions "Delete dat" and "Optimize database" have to be activated in this order!

7.2.20 3025 PCMCIA memory full

Cause

- The PCMCIA card has less than 8 KB space left for saving additional data

Remedy

- Delete data records from the PCMCIA card in order to free up additional memory capacity
 - insert the card into a PC that has a suitable port, export the data, and then delete the data from the card
 - reformat the card in the Roche OMNI C (see Reference Manual, chapter 3, "Operating modes", section "System – Test – PC Components – PCMCIA card")

7.2.21 3026 Data object error

Cause

- The data access onto objects in the analyzer area failed, the the correct operation of the Roche OMNI C can not be guaranteed

Remedy

- Press the "Reboot" button
- In case of recurrence, call customer service (the electronics is defective, change components if necessary)!

7.2.22 3028 Hardware error

Cause

- Electronic components do not respond properly

Remedy

- Wait! These errors are automatically self-repaired!

7.3 Electrode status

If a parameter is not ready (not calibrated), the symbol will be crossed out with grey and red lines (see Abb. 2).

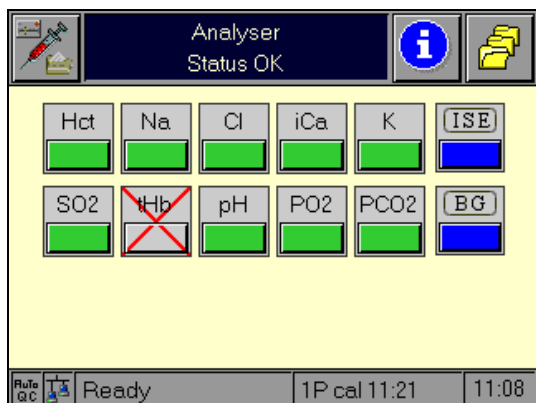


Abb. 2

After you press the parameter button, a status report will give you information about why the parameter could not be calibrated (see Abb. 3).

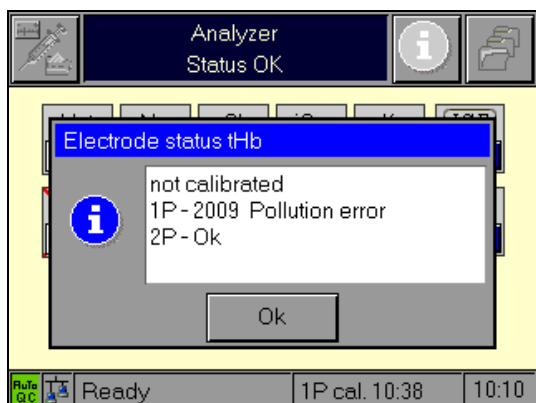


Abb. 3

Remedy for the example in Fig. 3

- Start "Calibration for Ready", see chapter 3, "Calibration".
- Exchange electrode, see chapter 6, "Maintenance", section "Exchanging the Electrodes and the MCon."
- Please see the Reference Manual, chapter 5, "Error Correction", for a detailed description of the short texts!

7.3.1 Sensor status

For additional information about the sensor status, press:



and "Sensor status"

Press "line up/line down" and select a sensor from the list on the left.

You receive the following information about the selected sensor:

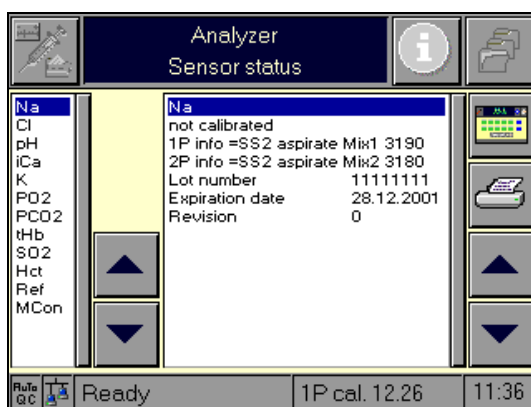


Abb. 4

By pressing , you can start the printout of the report.

8 Operating modes

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8 *Operating modes*

The Roche OMNI C is a combined bloodgas, electrolyte, and tHb/SO₂ analyzer. It is possible to complete database procedures or to make simultaneous adjustments during measurement or calibration.

The individual, mutually independent operating modes are defined as follows:

- Analyzer: measuring, QC, system, calibration, commonly used functions
- Setup: instrument settings
- Database: data about patients, measurements, calibration, QC, and the instrument
- Info: Roche info, version numbers, fill levels, help, sensor status

8.1 *Analyzer*

The "Analyzer" operating mode contains parameter information (for example, "Ready"), system settings, and the QC measurement. The highest level of this operating mode is the "Ready" screen.

8.1.1 *Parameter – depiction and buttons*

For a more detailed description, see chapter 1, "Introduction"!

8.1.2 *"Ready" screen*

The Ready screen is the central starting point for all operations. The instrument is usually in the "Ready" state.

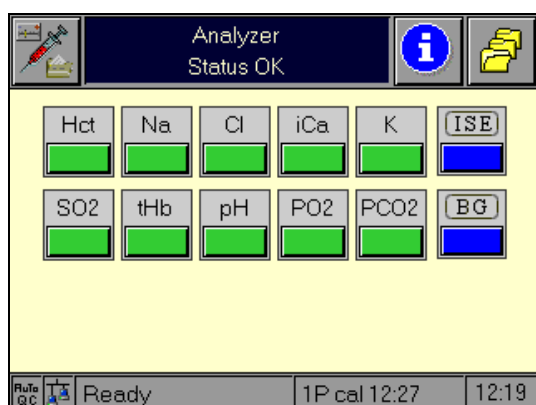


Fig. 1

If a "mandatory input" field has been modified (in the "Setup" operating mode), measurement can begin only after entering the data associated with this input field.

Every possible input value can be defined as a "mandatory input."

IMPORTANT: only one input value can be defined.

In the following example, the Specimen ID has been defined as a mandatory entry.

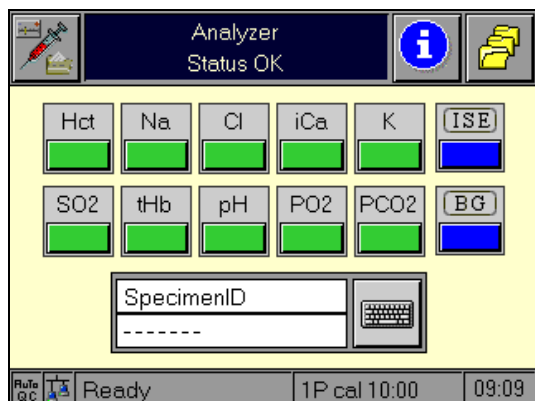


Fig. 2

Press the  button and enter the Specimen ID. The measurement can then be started. If the measurement is equipped with password protection, the "Ready" screen is covered by the password window but the parameter section remains visible (parameter information).

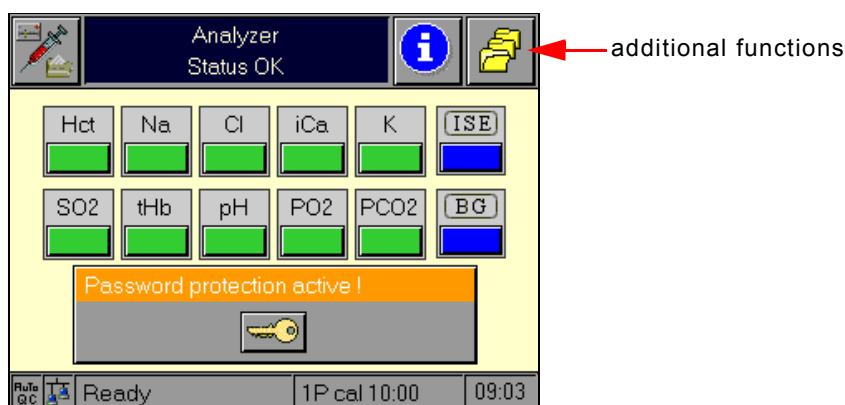


Fig. 3

Press the  button and enter the required password. The measurement can then be started.

TIP: When a mandatory input or password is activated and the flap is opened without completing the input, one of the following messages appears:
 "Complete mandatory inputs" or "Close flap and enter password."

The system section can be reached directly and only from the "Ready" screen.

This occurs by pressing the  button.

This button calls up a window with which the following functions may be activated:

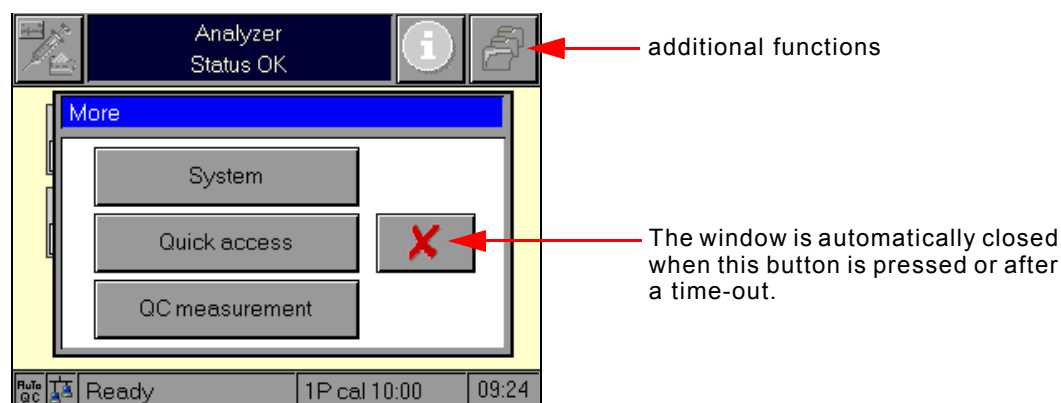


Fig. 4

8.1.3 System

The following main menus are available:

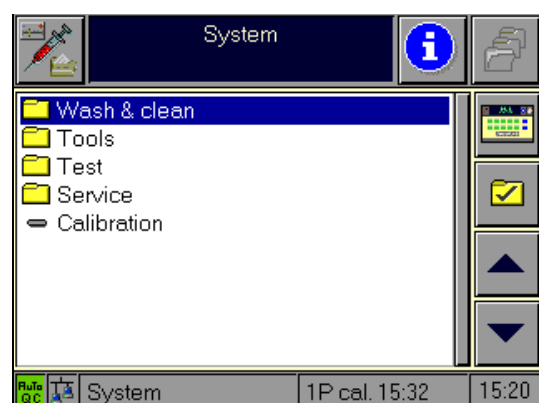


Fig. 5



Select the appropriate function.



Activate the marked entry.



Back to the top level of the analyzer mode (= "Ready" screen).

8.1.4 Quick Access

Using these functions, you can start the following actions or change the following settings:

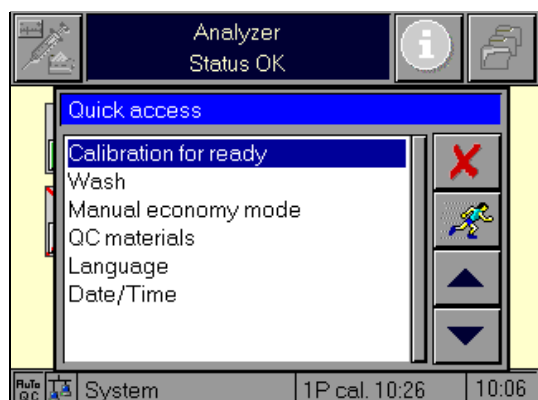


Fig. 6



Select the appropriate function.



Start the selected function.

8.1.5 QC measurement

This function helps start a quality control measurement.
For more detailed information, see chapter 5, **Quality control**.

8.2 Setup

Use this function to make the following settings:

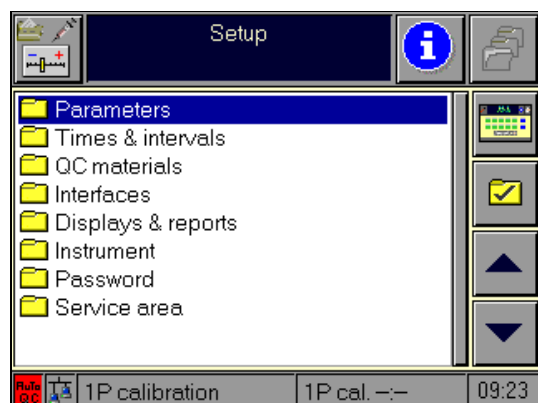


Fig. 7



Select the appropriate function.



Activate the marked entry.



Back to the top level of the analyzer mode (= "Ready" screen).

TIP: You can activate the desired setting directly by pressing the respective line on the screen.

Please see the Reference Manual, chapter 3, "Operating modes", section "Setup" for an exact description of this operating mode!

8.3 Database

Use this function to retrieve the following data:

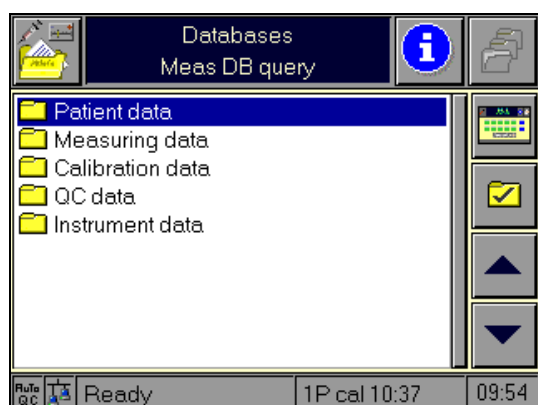


Fig. 8



Select the respective database.



Activate the marked entry.

TIP: You can activate the desired database directly by pressing the respective line on the screen.

The following query criteria are possible:

- Today
- Last week
- Last month
- All patient, measurement, calibration, QC, and instrument data

Description of the buttons and their function

The buttons described here are used only in the "Database" operating mode.

	mark	The completed line is marked, the cursor moves to the next line.
	search	This function enables the search according to search criteria in ascending or descending order.
	sort	This function enables sorting of records. <i>Sort criteria: Date / Time</i> (Only for measurement, calibration, QC, and instrument data) Up arrow - the records are arranged in ascending order (oldest date is at the top). Down arrow - the records are arranged in descending order (youngest date is at the top). <i>Sort criteria: OpID</i> (Only for measurement data) Up arrow - the records are arranged in ascending order. Down arrow - the records are arranged in descending order. <i>Sort criteria: patient ID</i> (Only for measurement data) Up arrow - the records are arranged in ascending order. Down arrow - the records are arranged in descending order. <i>Sort criteria: last name</i> (Only for measurement data) The records are arranged alphabetically according to the patients' names. Up arrow - the records are arranged alphabetically in ascending order (for example, from top to bottom - Z->A) Down arrow - the records are arranged alphabetically in descending order (for example, from top to bottom - A->Z)
	QC statistics	Only for QC data: The marked ranged is depicted as a Levey Jennings chart.
		Only for patient data: The measurement data associated with the selected entry is shown.

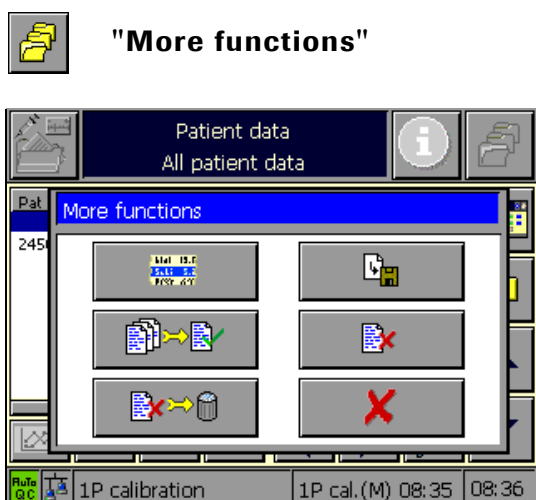
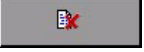


Fig. 9

	Export data	The marked data range is exported to a PCMCIA card or through an interface.
	Delete data	Delete the marked data range (see the Reference Manual, chapter "Operating Modes", section „Database > Delete data“).
	Screen shot of the database overview	A list of all available forms is displayed (user-specific and standard). This selection remains the defined standard until a new form is selected (see the Reference Manual, chapter "Operating Modes", section "Setup > Displays & reports - Measuring data > Measurement > DB - Overview").
	Optimize database	The database is optimized. More disc-space is available.

Data export – PCMCIA card (for example)

- Open the printer cover.



Fig. 10

- Insert the PCMCIA card into the port.

TIP: Please be sure that the card is inserted correctly (see Fig. 11)



Fig. 11

- Press  and then .

The following screen appears:

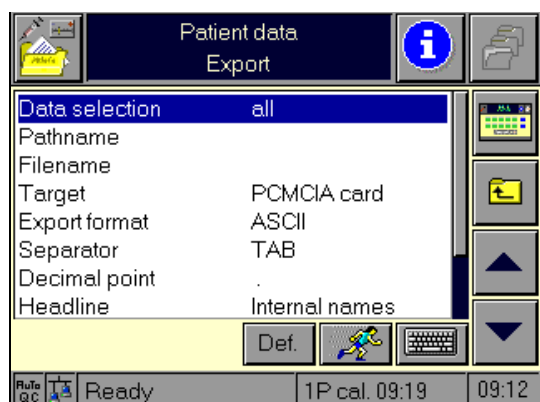


Fig. 12

- After completing all entries, press . The data is exported.

Please see the Reference Manual, chapter 3, "Operating modes", section "Database" for an exact description of this operating function!

8.3.1 Patient data



Fig. 13



Press these buttons to scroll through all parameters.



Select the marked entry - the patient's data is shown.

8.3.2 Measuring data

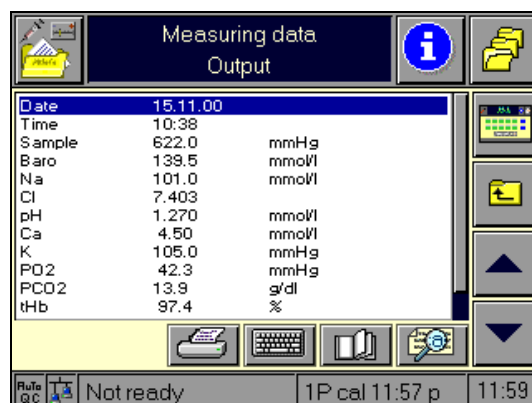
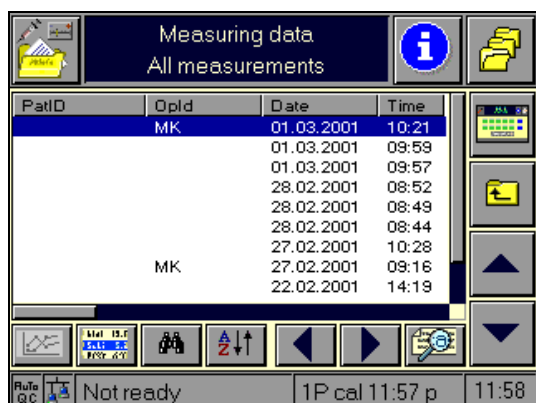


Fig. 14



Press these buttons to scroll through all parameters.



Select the marked entry - the results screen associated with this measurement is then displayed.

8.3.3 Calibration data



Type	Date	Time	Baro	E
System calibration	04.07.2001	10:48	730.1	0
1P calibration	03.07.2001	17:27	732.2	0
1P calibration	03.07.2001	16:44	732.2	0
1P calibration	03.07.2001	16:03	732.4	0
1P calibration	03.07.2001	15:21	732.6	0
1P calibration	03.07.2001	14:37	732.5	0
1P calibration	03.07.2001	13:54	732.6	0
1P calibration	03.07.2001	13:11	732.8	0
1P calibration	03.07.2001	12:27	733.1	0

Type	System calibration			
Date	04.07.2001			
Time	10:48			
Baro	730.1	mmHg		
Electrode performance				
Remark				
Na	727.77	mV	Ok	
Drift	0.0	mmol/L	Ok	
Slope	conditioning nok			
Slope drift	conditioning nok			
Cl	679.84	mV	Ok	
Drift	0.3	mmol/L	Ok	

Fig. 15

When you start this function, the Roche OMNI C displays an overview of the saved calibration data.

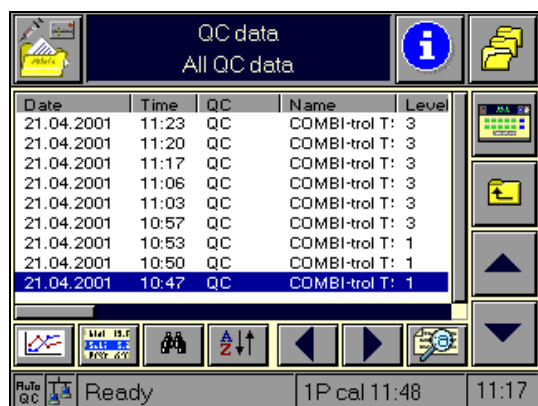
Every line displays a short record of a calibration and contains the date, time, type of calibration, as well as the parameter's condition after the calibration.

  Press these buttons to scroll through all parameters.



Select the marked entry - the results screen of this calibration is then displayed.

8.3.4 QC data



Date	Time	QC	Name	Level
21.04.2001	11:23	QC	COMBI-trol T: 3	
21.04.2001	11:20	QC	COMBI-trol T: 3	
21.04.2001	11:17	QC	COMBI-trol T: 3	
21.04.2001	11:06	QC	COMBI-trol T: 3	
21.04.2001	11:03	QC	COMBI-trol T: 3	
21.04.2001	10:57	QC	COMBI-trol T: 3	
21.04.2001	10:53	QC	COMBI-trol T: 1	
21.04.2001	10:50	QC	COMBI-trol T: 1	
21.04.2001	10:47	QC	COMBI-trol T: 1	

Fig. 16

When you start this function, the Roche OMNI C displays an overview of the saved QC data.

This screen shows you, based on selected query criteria, all QC materials that were measured up to this point, the level, lot numbers, and the date on which the QC files were begun.

After you have selected and completed an entry, press the "Zoom" button to receive all available information on the completed QC file. Every line shows the date, time, operator ID (when available), and the corresponding status of the available parameters.

  Press these buttons to scroll through all parameters.



Select the marked entry - the results display of the selected QC data are displayed.

8.3.5 Instrument data



Fig. 17

When you start this function, an overview of the saved instrument data is displayed.



Press these buttons to scroll through all parameters.



Select the marked entry - details about the entry are displayed.

8.4 Info

Use this function to retrieve the following information:

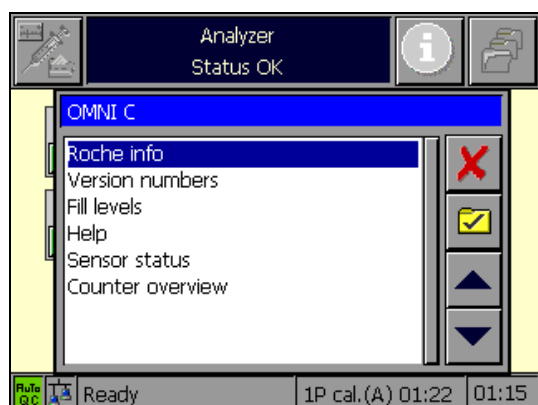


Fig. 18

8.4.1 Roche info

This displays the name, address, telephone number, and e-mail address that you defined under: "Setup – Instrument – Roche info" (see Reference Manual, chapter 3, "Operating modes", section "Setup").

8.4.2 Version numbers

This lists the software version.

8.4.3 Fill levels

Use this function to check the fill level (see chapter 6, "Maintenance", section "Daily – Check fill levels").

8.4.4 Help

Use this function to retrieve online-help information.

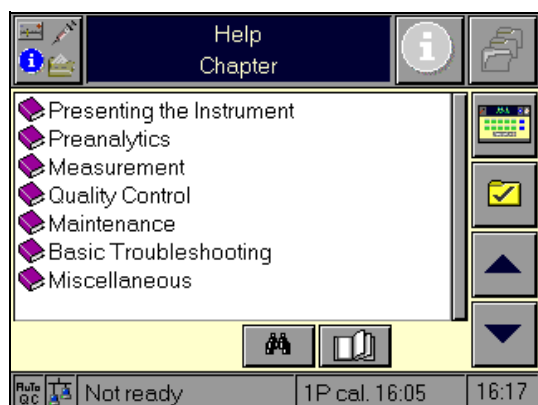
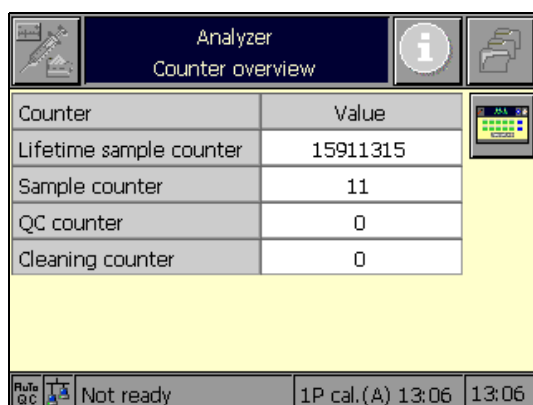


Fig. 19

8.4.5 Sensor status

See chapter 7, "Trouble shooting"!

8.4.6 Counter overview



Counter	Value
Lifetime sample counter	15911315
Sample counter	11
QC counter	0
Cleaning counter	0

Rule GC Not ready 1P cal.(A) 13:06 13:06

Fig. 20

Lifetime sample counter: Number of all measured samples since initial startup

Sample counter: Number of measurements

QC counter: Number of QC measurements

Cleaning counter: Number of internal cleanings

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